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„Modes of justification in bioethical opinion papers. How scientific societies try to govern the moral fabric of human reproduction“

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Acknowledgements

"It's not easy to see things in the middle, rather than looking down on them from above or up at them from below, or from left to right or right to left: try it, you'll see that everything changes" (Deleuze & Guattari, 2019/1987: 24).

… the path to a doctorate is a long one with many lessons to be learned, sometimes very difficult ones, sometimes even quite rocky and stony ones, and sometimes ever miraculously flowing and smooth ones (which feel as if a knot would suddenly loosen). In any case, it is an exciting and intense endeavor that brings a multitude of new insights and joys, especially concerning oneself. On this long path, I have grown into an exciting philosophical and research field called STS (Science and Technology Studies) and, along the way, I have met many people to whom I owe a debt of gratitude, because without this crowd, the whole enterprise would never have been possible!

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This work is dedicated to the wild thinkers …

Chapter 1: Ethics as ontological experiments: An STS-inspired analysis of bioethical decision-making in assisted reproductive medicine

Human in vitro fertilization (IVF) is a profoundly important advance in medical technology and one that serves to reproduce not just babies, but cultural values, understandings of gender and family, technological aspirations and goals, and research directions. The history of IVF is not only a history about technological advance, but essentially a history of how human societies understand themselves: politically, morally, and biologically. It reveals the changing relationships between technology, medicine, ethics, and politics. At a time when we are undergoing rapid technological changes that challenge our assumptions about who we are, "the question of how we should protect the values that bind us together is at a premium" (Franklin, 2019).[1] According to Sarah Franklin, these are the real "facts of life" we need to understand, and as always, they are more complicated than they seem. In the general field of biomedical options – or, to borrow a phrase by Benjamin Hurlbut, "emerging technologies" (Hurlbut, 2015c: 128) – the boundaries between what is normal and what is pathological, or between what is healing and what is improvement, blur. As a result, new ethical and political questions arise, namely, how science should be performed under these changing conditions and within increasingly ethical imperatives (Folkers & Lemke, 2014; Rose, 2014). Through the molecularization of biology and the development of assisted reproductive medicine, new and different forms of visibility (in the sub-microscopic range), and new sorts of biological entities (in-vitro embryos, zygotes, stem cells, gametes…) have emerged. So too have new technological possibilities of control and intervention (pre-implantation genetic diagnosis, embryo research, cryopreservation of gametes and other tissue and many more), and new socio-technical constellations (for instance, third-party reproduction, or cross-border reproductive care) in a co-productive manner.

With these rapid advances in human reproductive medicine and persistent controversy surrounding reproductive technologies, ethics has become a central part of both professional and public debates. Along with all this comes questions like, what does family mean in the present in the context of these technologies? Clearly, childbearing can no longer be solely seen as a destiny or the default model. In fact, biomedical technologies today are enabling a complete reconfiguration of the traditional human reproductive process. Assisted reproductive technologies (ART) are one of these medical technologies that have profound social implications for many areas of life: models of family, life planning (compatibility of family and career), gender roles, the way we understand life, family and human existence in general, and even how we understand medicine and technology and the value we attach to it (as a society quite generally).

The medical field of assisted reproduction is a value-laden area full of high hopes and deep fears and, at its roots, is a place where ideas of ethics, (techno)science, responsibility, morality, and accountability all become negotiated by different societal actors. When it comes to such

[1] See also here: https://www.thebritishacademy.ac.uk/blog/how-conversation-around-ivf-has-changed-over-50-years/ (accessed on 2nd June 2023).

emerging (or controversial) biomedical technologies, questions regarding their institutional places, legitimate speakers, responsibilities and related power dynamics arise. Such questions include: who or what is responsible for deciding how to define and classify these new techno-scientific possibilities and entities? Or: who and what is seen as the 'legitimate' way to responsibly delineate the boundaries of these emerging technologies and their applications? And: what are the guiding institutions and discourses that are steering these debates and thus regulations? What is the relation between science, law and legal policy when it comes to these anticipated matters of conflict?
Research on human embryos, which is one of the most prominent subjects of these debates, has been a space of lively controversy in recent decades. These debates revolve primarily around the buzzword of human enhancement, which is overcoming of the 'natural' limits of the human body by technical means. These controversies have taken place in different but also entangled forms and fora, such as media, law, politics, science, and ethics; and at different levels, such as intra-scientific discussions, science-society discussions, or science-law discussions, and, most importantly, ethical discussions about aspects of regulation. Of course, different aspects are emphasized in each setting, resulting in different discursive formations.

This study is particularly interested in one of these negotiation spaces: *bioethics as a specific discursive formation* that has consolidated into *particular forms of institutions* with *specific functions*, namely its *governance interest* in steering (through different means) the very questions and debates when it comes to these new or emerging biotechnologies and its regulation. The difference between healthcare systems and their logics play a crucial role in the development of bioethics. This can be seen by divergencies in which ways questions are raised, how issues become issues in the first place and for what reasons, and, most importantly, in what ways such issues are considered, discussed and negotiated in what forms and styles.
For example, the healthcare system in the US takes bioethics in a different direction than, say, in the UK; and, needless to say, the US is the country where bioethics emerged as a phenomenon by considering ethical aspects of new biotechnologies in the first place. Moreover, the US also played (and continues to play) a crucial role in the development of IVF and ART worldwide (Thompson, 2016). In general, similarities can be observed in the institutionalization of bioethics, but also differences, depending on the institutions and logics to which it is connected and in which it is embedded and expressed. Therefore, if someone aims to understand the expressions of bioethics expertise (its functions, forms and practices of knowledge production) it is necessary to investigate different institutions in which so-called (bio)ethics committees are settled.
There is also a dominant linking logic at work in the discourse of bioethics, namely a so-called *logic of choice*, as Annemarie Mol has aptly called it in a different context (Mol, 2008). In the logic of choice, there is a profound conflation of empirical evidence and ethics that is namely recognizable in the way that empirical evidence (so-called facts) is considered a sound basis for appropriate ethical decision-making. This is thus considered the prime determinant of decision-making on both sides, i.e., that of patients as well as of professionals/physicians. This reflects the belief that the right decisions and good care will automatically and unambiguously

result from scientific evidence, and thus the 'right' knowledge. Alexander Bogner, among others, has already pointed out the same tendencies that can be observed in other areas, for example, in political decision-making (which increasingly relies on expert advice) (Bogner, 2021). In such a logic of choice, a certain morality becomes expressed, too: Treatment decisions and patient care are only properly carried out if they are based on a certain kind of knowledge, namely scientific knowledge – which is knowledge produced on the basis of accepted and systematic methods and from which emerges what is generally understood to be facts.
In a similar vein, Kirsten Bell writes that *health* acts in this regard as a kind of meta-value or trump card that is sometimes used to disguise the basic political, moral, and economic arguments that are primarily about how people should think and live (Bell, 2017). This shows how revealing it can be to examine how these different approaches are adapted and translated into ethical arguments and materials as legitimizing and thus truth-telling strategies. What we can observe in parallel here is a kind of epistemological evolution of bioethics itself, which points to a new relationship between ethics and science which takes the form of the increasing use of empirical/scientific evidence for ethical arguments. Or, as Martyn Pickersgill has aptly put it: "(...) it is clear that science today is an 'ethical' business. The ways in which formal and informal ethical discourses and practices – what might be called 'regimes of normativity' – structure scientific work and the meanings ascribed to it (...)" (Pickersgill, 2012: 579).

Against this backdrop, I will now describe in more detail what my work is about, including the key aspects of my comparative case study, including the materials of this study, my research interest and questions, my approaches to investigating them, and a tour de table through the structure of this work. However, all of these points are intended to delve deeper and deeper into dimensions as the thesis progresses, borrowing primarily from Foucault's discourse understanding (and archaeological approach) as well as from Luc Boltanski's and Laurent Thévenot's pragmatic philosophy and justification analysis. Furthermore, my analysis of the bioethics discourse as a governance practice draws upon the theoretical and methodological tools of science and technology studies (STS). In this respect, I am primarily inspired by an actor-network theory-based (ANT) research style (following the actors and the connections they draw) and sensitized by an attentiveness of a co-productionist perspective, which is meant to examine the complex interweaving(s) of knowledge and norms in making up social order (Jasanoff, 2004).

1.1 Case study: Comparing two ethics committees and their document work in the field of assisted reproductive medicine

If one is interested in bioethics as a particular kind of governance practice, one must first look for the institutional sites where it has been consolidated and practiced. Bioethics has, at present, been consolidated into a variety of institutions, but which almost exclusively consider it in the form of committee work. The most prominent committees or commissions are

connected directly to government (or governmental bodies) such as the historical precursor: The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1974-78), which is generally considered as the first national bioethics commission. This National Commission was established under the National Research Act of 1974 and is best known for producing the Belmont Report. This report is the main basis for the Institutional Review Boards (IRB) that review research proposals involving human subjects. Another prominent committee is the Nuffield Council on Bioethics in the UK, but there are also other committees that are integrated into higher education and university structures. There are also clinical ethics commissions, such as 'Research Ethics Committees' (RECs) in the UK, or the US equivalent of the 'Institutional Review Boards' (IRBs). There are even those, like the one in this study, that are embedded in scientific societies.

All of these bodies[2] are primarily concerned with biotechnologies and the review and critical evaluation of research involving human subjects, i.e. the protection of individuals (in clinical research and practice) and other related issues that will be detailed in the course of this thesis. Through the broad composition of such ethics committees, and in particular, through the involvement of a wide variety of stakeholders in the medical field, they seek to ensure a high level of ethical and professional competence in the review of research projects and in the protection of the individuals concerned. They represent the most important or salient institutional sites of bioethical discourse and their decision-making.

Thus, how did I come to choose two particular ethics committees that are part of two international scientific societies in the field of reproductive medicine and reproductive technology: 1) ESHRE, the European Society for Human Reproduction and Embryology, and 2) ASRM - the American Society for Reproductive Medicine? At the very beginning of my PhD, it was a simple coincidence that I came across these two cases. My main interest has been, from the start, the increasing demand, or even the imperative, for ethical consideration in science more generally and in bioethics more particularly. And by this, I mean bioethical consideration of biomedicine and biotechnologies within different institutional environments.

Additionally, the field of reproductive medicine and its wide array of technologies struck my interest because it constitutes a crucial reservoir where bioethical debates ignite and burn. It is here where a range of controversial research lines and associated questions emerge, such as the IVF embryo and its connected research field of stem cell research, cloning, and gene editing technologies. Yet, further examples include pre-implantation genetic diagnosis (PGD) and with it the associated question of sex-selection. Or cryopreservation is a particularly noteworthy technology because it sparks plenty of questions directed towards the postponement of childbearing, which results in a so-called 'medicalization' of societal defects, such as incompatibility of family and career, to mention just a few.

Furthermore, there was another area of interest bound up in this topic, namely the novelty of how these particular bioethics bodies are assembled when compared to more traditional medical ethics. Specifically, they are occupied primarily (or also) by philosophers, lawyers, and

[2] For a quite exhaustive list, see for instance here: https://www.bundeskanzleramt.gv.at/themen/bioethikkommission/links-zu-bioethik.html (accessed on 4th April 2023).

social scientists rather than, say, medical scientists and/or natural scientists, such as geneticists. My point of departure here was to consider the question of insourcing and/or outsourcing of ethical issues in the field of biomedicine and in particular, assisted reproductive medicine. Or, to put my interest differently: who is actually designated as an authorized speaker in these ethics bodies and in particular: who is involved in the primarily written work they are doing?
Because I encountered these two big international scientific societies in the domain of ART, I realized that both of them have their own ethics working groups that are incorporated into the organizations themselves. Those working groups are responsible for producing ethical positions in the name of the entire organization; and they have had this structure for quite some time. The fact that I came across two organizations in the field of assisted reproductive medicine and reproductive technology (ART) has to do, of course, with the fact that it is a morally charged field in which many complicated ethical issues arise and that regularly surface in the media as well as in politics.

Furthermore, both organizations have demonstrated interesting relationships with each other. They are also located in different geographical and socio-cultural contexts, at least in terms of regulations and socio-political differences. Despite the fact that both ethics groups are part of two large international scientific societies, both are located in specific geopolitical areas: ASRM is located in the North American region, which is considered a supposedly more coherent or homogeneous state entity in both the medico-legal and cultural senses. ESHRE, on the other hand, is based in Belgium and is a European international organization, and it is located in a much more loosely connected legislative space of the European Union. However, the unity of a nation-state, as in the first case, does not say so much about the coherence and homogeneity of the legal regulation of a biomedical field such as that of ART, especially in light of a very pronounced federalism and high level of self-regulation. And conversely, the supposed heterogeneity of an amalgamation of different countries into one economic and political entity, as the EU, does not necessarily imply a chaotic and unregulated limbo.
Overall, it can be said that both legal situations regarding the regulation of reproductive technologies can be characterized as a kind of patchwork. This does not mean that it is not regulated at all, nor that it is over-regulated, but it does mean that it is difficult to give an accurate overview of what the regulatory situation(s) are in each European country or US-state (which is neither the task nor the aim of my PhD project). However, it is crucial to point out that exactly this regulative patchwork forms, in both cases, the medico-legal environment that builds an extremely fertile ground for both of these scientific actors to fill this space with their professional expertise. They do this by creating, guiding, and issuing (ethical) rules of practice and definitions, framing debates, and issuing expert recommendations in and for the field to gain prominence and play an important role in shaping and thus steering the field, its medical practices, and technologies.
In this regard, one particularly useful concept for my work is that of the ‘committee’. Referring to Kristin Asdal’s and Bård Hobaek’s (2020) considerations regarding issue-politics in the context of parliamentary work in Norway, the notion of the ‚committee‘ is actually an

interesting coinage in this context. To call such an expert body an committee (outside of parliament and governmental work) is precisely to indicate a specific role as issue experts, which relates to the very procedures or functions on how they come to their statements and conclusions. This shows that "The important thing here is how issue formation can be understood as a process already built into standard procedures, rather than something that emerges when questions escape routine handling" (Asdal & Hobæk, 2020: 259). Using the notion of the committee puts a particular emphasis on the procedural aspects of their work, which also becomes reflected in their outputs: the *ethical opinion papers* themselves.

Thus, in the course of my research, my analytical interest has primarily focused on the written ethical opinions, as well as other forms of their dissemination, including sessions at conferences and diverse workshops that these ethics committees engage in. This focus is because I argue that these are both relevant manifestations and appropriate objects to scrutinize.

My questions, in particular, include: Who does things (in the sense of studying who participates in these ethics committees) and, especially: *how* (and what) do these ethics committees conceptualize as their primary objects of ethical consideration? Further questions include: how they turn these things into particular issues; how do they modify them; which notions they construe to think through conflicts between knowledge and value questions; and, last but not least, which *modes of justification* they introduce to justify what ethically (un)acceptable (medical and/or research) practice should mean in the context of ART. It turns out that these *modes of justification* are 'statements' in the sense of Foucault – i.e. statements that are repeatable under specific conditions and therefore represent the central arguments (statements) in this discourse (Foucault, 1972). In terms of governance, the committees use these justifications to legitimize not only the individual technologies but also their ethical work itself. Because they come to their conclusions and recommendations not only on the basis of some opinion, but follow certain rules, forms of knowledge, and methods with which they built and substantiate their arguments. Following on from the conception of the case, I will now drill down into more specifics about my exact research interest and questions.

1.2 Research interest and questions: How document artifacts are scripted

The primary aim is to examine bioethics as a soft or tacit form of governance practice (Felt, 2017). In doing so, I focus in particular on *how bioethics is performed*, which directs me to focus on how the ethics committees of the ESHRE and ASRM negotiate, construct and argue the ethical acceptability of assisted reproductive technologies in particular ways and forms (focus: documentary productions). To further specify, it is more about emphasis than exclusion, which means that the conclusions and objects of bioethical deliberation and decision-making will also be of central importance. However, their importance will only be insofar as it is done through the detour of 'how' they consider producing those very objects and questions. It is rather a question of perspectivization, which is how my work tries to gain a view of the phenomenon of bioethics and to illuminate it from different angles. It will be necessary to return to this theme later on in order to further develop the perspectives of my thesis (especially in Chapter 5, but also the analytical Chapters 6 & 7).

With this in mind, my projects asks about the emergence, functions, and workings of bioethics in specific institutional environments, namely the aforementioned two international scientific societies in reproductive medicine: the *European Society of Human Reproduction and Embryology (ESHRE)* and the *American Society of Reproductive Medicine (ASRM*). I am particularly interested in the question of what it means to increasingly incorporate ethical considerations into epistemological and technoscientific practices in general and how this is done (i.e. in which ways and for what reasons) by these specific ethics committees.

From an STS-perspective, I have chosen to primarily follow the most obvious outcomes of these committees: their ***bioethical opinion papers***. These can be understood as quite lively actors, functioning as value generators and technologies of politics, that are relevant manifestations of a so-called bioethics discourse. They are also suitable objects to study exactly how things are made, as well as how conflicts between knowledge and value practices are conceptualized, in so-called ethical terms within these ethics papers. In this sense, I understand these particular documents in twofold ways (both of which are ANT-based). First, I follow Latour's understanding of a *semiotics of things*, in this spirit one just has to drop "the meaning bit from semiotics", which then translates into "path-building, or order-making, or creation of directions" and "one does not have to specify if it is language or objects one is analyzing" (Latour, 1996: 378). In a Latourian sense, documents can therefore be dealt with as things like any others:

> This move can be said either to elevate things to the dignity of texts or to elevate texts to the ontological status of things. What really matters is that it is an elevation instead of a reduction and that the new hybrid status give to all entities both the action, variety and circulating existence recognized in the study of textual characters and also the reality, solidity, externality that was recognized in things "out of" our representations. What is lost is the absolute distinction between representation and things (…). (ibid.)

Second, documents can be understood as technologies of politics and thus of power because they produce something that I will call at the very end of the thesis 'ethical evidence', which occupies governance functions and abilities. My work undertakes the methodological move to put documents, specifically the ethical opinion statements, centre-stage and views them as integral elements of making the very issue(s) at stake (Asdal & Hobæk, 2020), which means in my case concretely in the context of reproductive technologies.

Against this backdrop, I clearly follow Foucault's understanding of discourse, in whose vein discourses are understood as practices that systematically form the objects of which they speak. I view these written ethical statements as a particular practice and as crucial elements of a bioethical discourse. This discourse contains and performs a (soft) form of governance inasmuch as they formulate and establish 'rules', interpretations, justifications, boundaries and arguments for defining and understanding what should count as ethically (un)acceptable practice in the domain of reproductive medicine and its technologies. And just to presage it here, my document analysis is designed as a kind of statement analysis in a Foucauldian sense.

By viewing these documents in this way, they can further be comprehended as kinds of *inscription devices*, which reflects the work of Madeleine Akrich (1992). Among other things,

she has studied how innovators' visions of the world become "inscribed" into the content of technical objects, which led her to call the end product of this work a "script" or "scenario" (Akrich, 1992) and "[t]hus, like a film script, technical objects define a framework of action together with the actors and the space in which they are supposed to act" (ibid.: 208). In this vein, the ethical opinion papers can be understood as technologies of politics in which certain visions (about how to deal with these ARTs) have been inscribed. This raises the question of what the main aspects of this conceptualization of 'ethically acceptable practice' are and how they are performed and inscribed by these ethics committees into their ethics papers.

Furthermore, I centre my analysis particularly on the modes of justification that these committees put forward in their documents in order to also reflect on what these modes of justification actually do for their part in terms of their functions and appeals; in doing so, I follow Boltanski's and Thévenot's pragmatic philosophy. I will come back to these aspects in chapter 5 when I describe my research interest in relation to the case-study in methodological terms in more detail, and in chapter 6 when it comes to the empirical document analysis.

Bioethical opinion papers are critical actors to study because the written form is quite essential in bioethical decision-making. Incidentally, this is not only the case here but also when it comes to scientific policy advice more generally. The written form represents a very concentrated form of engagement with a topic and this depth of engagement with a topic in its various details is more readily apparent in written arguments than in oral discussions. The written word requires a much deeper and more intense engagement with a subject than oral discussion ever could, but only in the sense that it forces one to some kind of agreement and clarity through its representation. We find in them a fairly concentrated, coherent, and stringent form of discussing, arguing, and justifying issues as well as the particular practices in which they are embedded. This must be the case because only then can bioethics (and its ethical opinions with its arguments) serve and function, at least theoretically, as a template or framework that could be used in policy making or in professional contexts, such as in clinical use or in physicians' practices. In this respect, these papers could also be seen as kinds of boundary objects in the sense that they deal with medical technologies and their ethicality from a tangled double perspective: once from a professional point of view (medico-ethical) and once from a regulatory point of view. Thus, as some would put it, they also have an experimental and therefore a kind of non-binding character that makes them just so attractive (Bogner, 2005; Gehring, 2016).

Moreover, something like 'history' or our understanding of the world (and how it works) is revealed to us to a large extent through the written tradition, which is a specific form of 'representation' (but which also constitutes a thing in an ANT understanding) that needs to be explored. As such, they also operate as a power technique in a Foucauldian sense. This is not meant in a purely negative sense but instead in the sense of a governance (steering) tool that makes something productive, i.e. enabling something (and in which direction this goes in the case of bioethics remains to be seen). The opinion papers function precisely as kinds of inscription devices to steer discourse(s), namely in the way how they grasp, embed, delegate, and modify the very objects and terms that are negotiated within this specific bioethics discourse.

As such, bioethical decision-making can or must be viewed as a phenomenon of governance, which I will scrutinize from a co-productionist perspective. Hurlbut, who has analyzed bioethics and its expressions in the US context in light of the human embryo debates, noted: "Bioethics figures centrally in my story, not as a set of principles for normative decision making, but as an emergent domain of thought, a reservoir of expertise and authority, and a new apparatus of governance" (Hurlbut, 2017: 33). In my view, however, this does not inevitably imply that one has to investigate the 'background' deliberation process of a committee, although this is, of course, a worthwhile undertaking that has already been accomplished by some STS scholars (Hurlbut, 2017). Instead, I want to examine the material form, that is, how a consensus and its deliberative process are manifested and expressed in an ethics paper. My interest lies exactly in these manifest outcomes of such deliberative processes, whether and how a committee intelligibly integrates value pluralism into these papers.
If one follows the documents as actors, potential lines of inquiry and self-drawn connections in this regard would include: Do remain different perspectives (and which ones) visible in such documents, or not? If so, how they are made visible? To whom should those documents be addressed and for which purposes? What are the characteristics of these documents, in terms of structure, language, argumentative practices and resources (such as argumentative modes of justification)? This also includes the investigation of the different structural sections of those opinion- and other related papers, which very often include sections that give some insight into cooperation, expertise and 'conflict of interest' issues, such as 'Acknowledgement', or 'Author contributions'; or even how the group in general frames the occurrence of a consensus, or a potential dissent on an issue within such an opinion paper. Furthermore, which rhetoric and linguistic styles do they present – more a policy, academic, or research style? To which other types of documents (from other organisations, international declarations, legal documents) and authors do they refer? And which function do these documents have (or aim to have)?

This is a classical matter for the *sociology of knowledge* and *STS perspective* that deals with questions of the intermingled nature of knowledge production and its normative conditions. Thus, I address the following questions in the course of this work:

Research questions:

1) How do the ethics committees of scientific societies construe and justify what they deem as ethically (un)acceptable practices and morally justifiable decisions and positions in the field of medically assisted reproduction?

2) Consequently: How and when do they apply different (argumentative) modes of justification and/or other resources (or mechanisms) in defining what should count as ethically (un)acceptable research and clinical practice in ART?

3) And finally: What role do these scientific societies see for themselves when it comes to defining what counts as ethically (un)acceptable research and practice?

While the first two questions address the documents quite explicitly as lively value actors (Asdal, 2015b) themselves, which will result in a detailed statement/justification analysis, the third one rather aims at the more general question of self-regulation (or: governance in a broader sense). I assume that an attempt can be made to answer this third question about self-governance through the other two questions based on the ethical opinions, but also on the field visits at conferences and conversations, which I conducted and will discuss in more detail in chapter 5.

In the context of my work, the difference between morals and ethics is not a crucial one, but I deliberately decided to call it 'morally justifiable decisions' (in the first research question) because the ethical opinions indeed set values like scientific knowledge as a reliable basis for ethical considerations, or informed consent, that is, patient autonomy in the form of patient choice, as commonly shared values. The bioethical opinion papers not only present an ethical consideration or evaluation of what is right and wrong in medical and research practice in ART but also promote or acknowledge something like 'secular' values upheld in democracies or even in Western medicine and health care.

Furthermore, I claim that the self-perceived role(s) of these societies can be analysed through the document work of their ethics committees because such roles become actually reflected precisely through the justificatory work that they perform in them. But not just in the documents but also at their conferences, one finds impressive insights into their diverse work and membership and the multiple relations they socialize with different other actors (such as the pharma industry, biotechnology companies, a broad and diverse medical profession, and policy makers).

1.3 Some more notes on methodology and conceptual lenses

In addition, my project is also interested in the question of how and why bioethics has emerged as a specific discourse alongside other existing fields or discourses, such as law and politics, or even the social sciences (such as technology assessment). In the individual chapters to follow, I will approach this question via the 'how'. This means what and how bioethics works, argues, and most importantly, how it *justifies technological interventions* in the field of assisted reproductive medicine and thus, in which ways it offers specific answers. Similar to Foucault, I believe that this approach or perspective (how it works and operates) also allows for conclusions, or at least hypotheses, about the 'why' (the reasons) of its emergence. Therefore, my project is also about the specific institutionalized forms of the bioethics discourse, focusing on specific institutional sites and spokespersons, and it deals especially with its typical outcomes (so-called *bioethical opinion papers*) as important instruments with specific functions, operating as potential governance devices.

Thus, I am interested in why bioethics – as a particular discursive formation around new and emerging biotechnologies – is such an appealing actor: Why has it emerged and for whom does it provide appealing answers and to what questions are those answers given? A discourse analysis in the Foucauldian sense, with an explicit co-production perspective, seems to be an

appropriate way to answer such questions. This means an attentiveness to the complex interweaving(s) of knowledge and norms in making up social order and how they are drawn by the actors themselves. Methodologically, this is done in the form of a justification analysis, which is designed as a kind of detailed statement analysis of the ethical opinion papers.

With regard to the various conditions of bioethics emergence and its manifestation as governance practice, Hilgartner and colleagues (2017) demonstrated, albeit they engaged rather with ELS (Ethical, Legal, Social) programs as science governance, that there is not yet a large, theoretically informed literature on ELS and bioethics as a form of governance and what its emergence means. Further, most studies do not develop historically informed studies, and in my opinion and accurately noted by Hilgartner and colleagues, "(…) do not develop *longue durée* histories, and most do not take up the leads provided by the existing sociological analyses of bioethics, historical accounts, or works in political theory on science and governance (…)" (Hilgartner et al., 2017: 840). Hurlbut, for instance, has made it clear that when you put the analysis of bioethics under the perspective of governance, it is also about the idea of the future and how we want to live:

> At the center of this task of governance is the question of how we imagine the future—in what terms, how narrowly or broadly, how inclusively or exclusively of alternative and dissenting imaginations? Governance, for all its vagueness, is an apt word for this task. It is a nautical term that in its ancient meaning meant to steer. If we think of governance as steering the ship, we need to ask what trajectory we are on and sailing onward toward what uncharted future. Who is navigating at the helm, and with what instruments? The question of how we should navigate is fundamentally a democratic one. In orienting ourselves to a technological future, we as a society assume postures in the present—toward ways of knowing, ways of reasoning, and ways of experimenting with our techniques of navigation. Imagined technological futures come and go, but it is these postures, embedded in institutions and codified as precedents, that become durable features of our world. (Hurlbut, 2017: 272)

However, it is not just about the heterogenous elements of steering the ship, from time to time, it can also come to pass that the ship itself changes too. Furthermore, some scholars highlighted the importance of comparative research which shows the manifold cultural differences that are involved in reasoning and governing technologies in society (Felt & Fochler, 2010; Jasanoff, 2005). To draw once again from Hilgartner and colleagues, "Clearly, there is a need for additional critical investigation of ELS and "ethics" as modes of governance, with attention to variation among cultural and political contexts" (Hilgartner et al., 2017: 840). This also implies that one must analyse bioethics in relation to institutions, discourses, identities and dispositions of power when aiming to understand current shapes of ethics (as) governance. This project tries to address some of these facets by studying and comparing two concrete ethics committees that are embedded in particular institutional, organisational as well as politically and culturally diverse environments.

These are the reasons why I decided to conduct a qualitative comparative case study. One crucial methodological entry point of my dissertation project (2016-2019) has been that I attended a number of conferences (annual meetings), symposia, and workshops held by these societies (especially of ESHRE), where I conducted participatory observations, and had a number of conversations with different members of these societies (for more details, see Chapter 5.3). The important glimpses into these societies that I gained during this exploratory

phase gave me a general, but at the same time very sensitized, view of this medical community in reproductive medicine. It allowed me to grasp the diversity of members, institutions and companies involved in this community and represented at these major international medical conference events.

However, the particular *focus of my comparison* is based on a *document analysis* that examines in detail the main ethical opinions of the two ethics committees of the EHSRE and the ASRM. These ethics papers can be considered as kinds of strategic documents in the context of these organizations in the sense that they are of great importance to their organizations as a whole. Their importance is both in terms of their function as a central positioning device and justification work on controversially perceived issues in ART. Yet further, they are also important in terms of the expected effect they intend to associate with these documents, namely to also address diverse publics, but especially medical practitioners and policy makers, sometimes explicitly, sometimes more implicitly (which falls into the scope of Hurlbut's description of governance and steering activity).
Accordingly, I am interested precisely in the particular *form* of these official and accessible *ethical opinion statements* and their functions. Preceding negotiations of the ethics committees enter the world precisely in the form of these official documents as objects (it's the way they get their shape), which are (theoretically) accessible to everyone and of which they can make use. Therefore, I consider this written form as a document object to be the relevant one to analyze. I follow the documents and their inner workings as actors, so to speak, and therefore focus on their particular modes of order that are enacted by them.
This approach, then, asks what these particular documents do, what they offer, what they reflect, what has been inscribed into them, to whom they supposedly belong or to whom they are supposedly addressed, and for what purposes they are intended. To do this, it is necessary to examine these document objects as lively actors themselves and to question what they do and what functions they thus (might) fulfil at this (more) manifest level.
Against this backdrop, the various *modes of justification*, as have been revealed quite convincingly by the document analysis, figure as central ordering elements in these ethical opinions. They operate as support and concretization of these medical technologies and interventions in ART that they are desirable and worthwhile to further pursue. Examples of these modes of justification include *evidence-based arguments*, *principle-based arguments* as well as *the informed consent procedure* (IC) as a discursive argument to protect patient autonomy. These modes of justification and how they are performed by the ethics committees of ESHRE and ASRM will be especially analyzed and detailed in chapter 6.

These ideas form the main methodological (entry) points, threads and framings of my work. However, these methodological considerations cannot be separated from its theoretical framing in a strict sense. These levels are tightly connected and thus the separation in this work merely serves a representational need: writing a monograph in a seemingly linear way. That this is not the case (and cannot be the case) is obvious, especially if one follows and takes the ANT principle of following the actors and their drawings seriously: "a very crude method to

learn from the actors without imposing on them an a priori definition of their world-building capacities" (Latour, 1999: 20). The conceptual considerations always have to go hand in hand with the methodological operationalization, and vice versa. So, how can I get to the thing I am interested in and to which directions do the actors lead me? This means that the method and concepts must also always remain fitted together to serve the respective research interest and object of study, which is in any case – in my ANT understanding – to allow enough space for practical ontologies.[3] My work tries to make these multiple connections tangible throughout the chapters. Thus, there are two intersecting levels, each consisting of three chapters:

Part A: *"Conceptualizing the Issue at Stake: The Co-production of Knowledge and Ethics. An STS-perspective on Bioethics"* details in three chapters the broader strategic thrust of my work, namely using the guiding question: *how to understand bioethics*? Here, as already mentioned, I follow primarily a co-productionist perspective and Foucault's understanding of 'historical' discourse to come to terms with bioethics as a particular discursive formation with certain functions, and thus, as a tacit form of governance practice. A co-production perspective focuses more on the normative discourses around technoscientific objects (or technologies) and takes them as vehicles for analyzing knowledge production and the power dynamics involved. However, this perspective cannot be separated from also looking at what specific actor-network, so to speak, is drawn in them to ontologically stabilize these technologies. This relates to the title of my introduction, which I have called "Ethics as ontological experiments", because ontological politics (Mol, 1999) raises not only the question of how politics is or becomes inscribed into technologies (or technological devices), but it is also about the emergence of multiple options and versions of objects and potentially new political forms that follow from certain technological arrangements (Jensen & Morita, 2015). Ethics as a particular discursive arrangement can therefore be seen as such a field of experimentation. It does not 'merely' reflect on a status quo or inscribes current way(s) of dealing with technologies (in this case ARTs), but through its idiosyncratic ways of thinking and reasoning, it produces potential future approaches to dealing and interacting with these new or emerging technologies – in other words, it conveys vivid (but not necessarily binding) offers for medical and/or political decision-making.

Part B: *"Analyzing Ethical Opinion Papers: How (Self-)Governance and Modes of Order are Enacted in the Bioethics Discourse",* tries to operationalize the broader framework by analyzing the concrete cases: the ethics committees and their work in the context of their institutional environments, by focusing primarily on their ethical opinions. Here I primarily follow Boltanski's & Thévenot's justification analysis when it comes to the inner workings (modes of justification) of the ethical opinions as document artefacts. I view documents as actors through an ANT-based lens, mainly following the understanding of Kristin Asdal and colleagues who view documents as lively actors that are significantly involved in producing world(s) and their

[3] However, we are part of that ontologies from the beginning, since we as scholars (have to) make innumerable decisions just like our actors that we decide to follow. I will come back to this point in the discussion part (Chapter 8).

understandings. When it comes to the comparative dimension of my project, I follow Akrich's and Rabeharisoa's understanding of qualitative comparison as well as other many valuable contributions in this direction. And when it comes to the strategic dynamics and ruptures that connect these papers and the bioethics discourse in general, I follow Mol's analysis of a logic of choice as a broader and dominant, and thus powerful connecting logic within Western healthcare systems, which is also reflected within these ethics papers of these committees. The goal is to analyze how the three modes of justification, as well as ethics papers more broadly, are interrelated with this powerful logic of choice. It also poses the question of what care might mean; or, to put it differently, what is missing from this logic when arguing only from the standpoint of patient choice.

1.4 Roadmap through the thesis

Finally, I present an overview of the structure and the individual chapters on the basis of which the dissertation is organized. The first part (**Part A**) is divided into three main chapters:

Chapter 2: "The Bioethics profession and its development over time" focuses primarily on the emergence of bioethics as a 'new' developing profession and is oriented towards the question of *who is authorized to speak* in this discourse. Here it is critical to look at the relationship between the public and professional interests that bioethics has claimed to balance and the prevailing narratives in which bioethics has become embedded. A further central aspect will be considering literature about bioethics as a new emerging profession, as well as the particular aspect of what actually makes a profession a profession. According to a widespread thesis in the sociology of professions, this is primarily based on their own way of finding and offering unique answers to problems – i.e., a unique way of reasoning (arguing). In this context, the question of which societal problems ethics committees actually offer solutions to is also crucial. The so-called principle-based approach within bioethics can be seen as a common or even hegemonic way of speaking (i.e. ethical argumentation) that has decisively shaped the bioethical discourse and its profession. It has provided a unique way of negotiating and enacting the very issues at stake.

Chapter 3: "The institutionalization of bioethics and its discourse" focuses primarily on Michel Foucault's concept of a discourse. In doing so, I focus predominantly on the common mode(s) of speaking within this particular discursive formation, as well as the various forms of institutionalization of bioethics (and how those aspects relate to each other, or in other words, how they co-produced each other). I develop a viable understanding of Foucault's concept of ('historical') discourse by applying it to the bioethics discourse. This means that I focus specifically on the particular ways of speaking and the creation of legitimate spaces in which biomedical issues and technology in ART become *bioethical issues* in the first place. I will also discuss how this particular bioethics discourse is related to the specific kind of institutionalization of bioethics, namely its consolidation into the form of ethics committees.

Chapter 4: "Bioethics and governance" develops an understanding by which bioethics can be viewed as a governance practice (i.e. ethics as a kind of policy field). This chapter problematizes the important but equally complicated relationship between bioethics and public policy. Here I address the broader frameworks in which bioethics is embedded, including a discussion of the changes that have taken place in contemporary Western health-care systems, which is often described as *(bio)medicalization*. This will be followed by a brief problematization of the conditions that have led to *medicine* becoming *biomedicine*, which actually opened up the space in which bioethics could emerge as a special kind of governance practice. In this regard, I will consider relevant literature that explicitly problematizes bioethics as a *governance practice*. In this respect, I will specifically highlight those moments upon which one might focus when studying bioethics as a governance practice, which are its functions, institutions and outcomes. Another sub-chapter here deals with the so-called "empirical turn" in bioethics (Ashcroft, 2003), which is about using empirical (social) scientific methods and also epidemiology, to gain empirical evidence for ethical reasoning and decision-making. If we want to understand what bioethics does, rather than what it is, we need to conceptualize it in Foucauldian terms and view it as a discursive technology of social control (Montgomery, 2016).

The second part (Part B) presents the operationalization of my conceptual thinking and develops an analytic for understanding bioethics as governance practice. It is divided into three chapters and will conclude with a discussion chapter on *ethical evidence*.

Chapter 5: "Analysing the materiality and modes of order in bioethical opinion documents: A qualitative comparative case study" introduces my methodological approach, which entails a comparative case study mainly centered around a comprehensive document analysis. Here, I lay out the key methodological threads that have guided my research approach, including the development of my ANT-based understanding of a qualitative comparative case study. It also contains the presentation of the two cases – the ethics committees of the ESHRE (European Society of Human Reproduction and Embryology) and the ASRM (American Society for Reproductive Medicine) as well as my research material. This material includes observational data at scientific events and conversations with key actors at these events, as well as a comprehensive document corpus of ethical opinion statements from both of the ethics committees of ESHRE and ASRM. I conducted the main part of my empirical research, the collection of material and its analysis, between 2016 and 2021.

Chapter 6: "Bioethical decision-making and its modes of justification: Arguments and other procedural modes in the bioethics discourse of two ethics committees" opens with an analysis of some important procedural modes of justification when it comes to the ethics committees' work, including, how the committees are assembled and their rules of deliberation. Then it proceeds with a detailed document analysis of the ethical opinions produced by the ethics committees of EHSRE and ASRM, which largely follows Kristin Asdal's understanding of documents as technologies of politics (Asdal, 2015a) and lively value agents. My analysis is further based on Luc Boltanski and Laurent Thévenot's pragmatist sociology (Boltanski &

Thévenot, 2006) of analysing how people justify acts. In this chapter, therefore, I present primarily a comparison between the written work of the two ethics committees, focusing on the *argumentative justificatory* work in their ethical opinions. It is here that I scrutinize the different aspects of their written bioethical decision-making work by focusing on how they come to define, classify and thus, justify what should count as ethically acceptable (and in rare cases, unacceptable) medical and/or research practice in the field of reproductive medicine. In doing so, my analysis concentrates on how they come to define, classify, delineate and shape various issues, in short, how objects are made and transformed through their particular justificatory work in and through these documents. Consequently, this thesis makes the methodological move to put documents (the ethical opinion statements) center-stage and view them as integral part of making the very issue(s) at stake (Asdal & Reinertsen, 2022).

Chapter 7: "Strategic dynamics and ruptures in the bioethics discourse: Bioethical issue-making in the context of wider healthcare logic(s)" then conceptualizes the justificatory work done by these ethics committees in the context of wider healthcare logic(s). Here I am oriented towards Annemarie Mol's framework of the two *logics of healthcare* (logic of choice vs. logic of care) by problematizing (again) the problem of *patient choice* and the potential meaning of *care* in the context of such written bioethical decision-making work. Here, the perspective is primarily directed to how the discourse of bioethics forms its objects; which evaluations this particular discursive formation allows; which terms and linguistic patterns the discourse provides and – this seems to me the most important here – which linking logics (a logic of choice), and by which themes and strategic elements its field of statements is permeated, which condenses into a very specific discursive formation.

Chapter 8: "Ethical evidence: Ethics as hybrid space of conflict transformation", in the last step, draws together the various threads I followed throughout this thesis on the local expressions of this bioethical discourse formation (i.e., the two specific and situated ethics committees in the field of reproductive medicine and technologies). Here I stress that questions of justifications are always connected with interrupting certain processes of communication and thus creating gaps for reflection(s). Hence, we can ask more generally about bioethics and its functions within a given democracy, and its relations to other fields of thought and argumentation, such as law, politics and even science itself? Seemingly, the bioethics discourse has actually emerged, fitting quite nicely into our relation and understanding of technology as a society, because it tests which kinds of justifications for technology intervention and conflictive matters could actually work in society. In this very sense, it constitutes a kind of ontological experiment because it probes and justifies this (permanent) mode of real experiment in society (in this case application and intervention of and through ART) that forms the very objects and issues in the first place. In this regard, I also say something about a striking characteristic of this discursive formation: its current lack of a concept of technology that goes beyond individual reproductive technologies around which bioethics usually groups and orders its problems and conflicts.

To close this roadmap, I summarize at this place the perspectivization of my interlocking and therefore complementary thrust of my thesis: the two parts with three chapters each (and a final concluding one) reflect this perspectivization. Just to recall Foucault's understanding of epistemology and its emergence: epistemology (or sciences) does not emerge somehow from experience but as an order of 'discourses'. It forms itself decisively in the form of *orders of speaking*. This insight is anything but trivial because it points to the fact that it is only these certain (discipline-typical) orders of speaking that make it possible "through which the systematic reference to something like experience is organized in sciences" (Gehring, 2004; 47, translated by the author).

That is, sciences or disciplines are not just any epistemological orders, but "discursive orders" (Foucault, 1974) in the first place, that is, orders of particular speaking that constitute on propositional 'truth' and thus, they are based on a series of techniques of exclusion, reassurance and I would add, indeed justifications (because those are the elements that are enabling something, namely a particular reasoning and understanding). This is what Foucault calls the discursive ordering character of truth, which sciences tend not to think about. With the perspective of co-production, however, STS-scholars try to place precisely this ordering character at the focus of the analysis. This means the *coproduction of the factual order and normative order* and therefore directs our gaze to the *modes of order* as well as to the *processes of order* (so how is ordered and assembled, or to put the German word for this process here: 'anordnen'). Hurlbut has noted in this regard:

> "It is only once we fully recognize the forms of power and authority that shape our thought-world that we can confront the question of "What we should do?" with enlightenment. It is this project of understanding that this book seeks to advance"(Hurlbut, 2017: 32).

In these processes, there is always an "economic of power" (Foucault, 1976) involved, whereby it is not the content per se, which is the deciding factor, but rather the form of power (its regimes, economies and thus its expressions) that becomes articulated within these epistemological discourses. My project contributes to this kind of inquiry. In this sense, it is a normative project as well, because it is dedicated to advancing this very understanding of the functions of discourses and the coproduction of science-society-technology relations.

A. Conceptualizing the Issue at Stake: The Co-production of Knowledge and Ethics. An STS Perspective on Bioethics

Ethics is currently the general modus operandi for discussing controversial technoscientific issues, as was already the case, for example, with genetically modified organisms (GMOs), synthetic biology or other biotechnologies. This has led some authors to speak of an increasing ethicization of technology, as well as a technicization of ethics (Bogner, 2015). Alexander Bogner, for example, in his research on national bioethics committees (in German-speaking countries), found that this increasing ethicization of technology conflicts – as he calls the transformation from a risk framing to an ethics framing – has led to both a change in expertise as well as a change in conflict structures in public controversies (Bogner, 2005).

With regard to biomedical applications, this very ethicization shifts the focus away from conflicts of interest and toward a conflict of knowledge and values, i.e. it does not only address questions of concrete applications, as it was the case, for example, with nuclear energy, but it instead addresses fundamental questions of what things and processes we actually want to know and ought to tinker with (as it is also the case with reproductive technologies).

In Bogner's analysis, this means that these different framings of conflicts have emerged because of different levels of abstraction. Questions about conflicts are then treated differently because the associated problems and social issues are no longer as directly connected to people's daily lives as they were, for example, with the issue of nuclear energy or other technologies. This is one of the reasons why these conflicts are negotiated in expert forums rather than in public arenas. Bogner speaks of "laboratory conflicts" in this context precisely because of this high level of abstraction, which includes topics such as cloning, research on human embryos, human genetics, egg freezing, and many others. These expert forums aim to first create a social basis for debates (structuring debates) in which people can then participate in the first place. This consequently leads him to speak of an increasing *scientification* (or *epistemification*) of value conflicts, which (paradoxically) increases scepticism towards experts. However, this is also an indication that professional societies are taking on an increasingly important role in regulating and upholding the ethical, educational, scientific and practice standards of the medical profession in the case of reproductive medicine. And not only here, but also in shaping public debates, they are playing a significant role. Therefore, I think it is necessary to examine the particular spaces in which such conflicts or debates are negotiated by experts or professionals themselves by using specific languages, i.e. ways of speaking and modes of justifying, and approaches to arguing and justifying medical and research practices in the domain of ART.

Chapter 2: The bioethics profession and its development over time

In historical terms, the emergence of bioethical considerations within the scientific and biomedical professional spheres can be classified as a novelty. Hence, the novelty of bioethics when compared to former (traditional) medical ethics persists specifically in the idea that ethical considerations are no longer considered to be the exclusive preserve of doctors – a professional guild who was considered best capable of determining what constitutes good conduct in their own field (Chadwick & Wilson, 2018). Thus, it indicates the emergence of a new group of professionals or experts who are particularly authorized to speak about bioethical issues. It heralds a transformation in the management and understanding of medical and scientific ethics, and thus, in the governance of (bio)medicine – and a supposedly growing external scrutiny of biomedicine, its science and research practices.
In the following sections, I will discuss the relevant aspects in the development of bioethics, its profession, and its institutions, and problematize the dynamic entanglement between medical self-regulation and external oversight by drawing on relevant sociological and STS-literatures. I will also partly draw on historical accounts written by so-called *bioethicists* themselves, or those with a close relationship to them; the latter type of literatures is particularly interesting in this case because it gives a better insight into the accounts, the narratives and who is considered legitimate as an authorized speaker to talk about bioethics and its development.

2.1 The birth of bioethics as (external) oversight of biomedicine? Some prevailing narratives on navigating between public and professional interests

During the 20th century, philosophers, lawyers, theologians, and even lay representatives began to engage with medical ethics with the aim of confronting, but also confirming, the authority of physicians (and biomedicine quite in general) by clarifying the ethical and legal aspects of hotly-debated topics such as IVF and the embryo debate, stem cells and many more primarily in the form of committee work (Wilson, 2011). This was also for example the case with the moral philosopher Mary Warnock in the UK, who chaired a government inquiry into human fertilization and embryology between 1982 and 1984, and who became a quite prominent figure of UK-bioethics and this particular form of oversight:

> From the outset, this new form of oversight was as concerned with legitimating research as it was with ensuring public accountability. And this reaffirms Rosenberg's claim that, contrary to its 'origin myths', bioethics is not, and has never been, a 'free-floating, oppositional and socially critical reform movement' (1999, p. 38). In Britain, as elsewhere, it was ultimately about bridging divides, not exacerbating them: deriving workable solutions without fundamentally questioning the forms of power or control invested in modern biomedicine. (Wilson, 2011: 137)

It is during this time when public scrutiny of medicine and its practices arose because of declining political and public trust. Starting somewhere in the 1960s and 1970s (but very likely earlier, perhaps even in the Post-War period as a result of heavily disrupted societies that experienced the atrocities of the Nazi-regime) as a consequence of eugenics, a series of research scandals, and moral dilemmas resulting from new medical technologies and

treatments, bioethics started to constitute itself as a kind of new profession and oversight mechanism. In particular, M.L. Tina Stevens, a historian, has shown that this dominant rationale of the history and social function of bioethics "(…) misidentify both the temporal genesis and historic social function of bioethics" (Stevens, 2000: xii). And further:

> Locating bioethics' latter-day roots more accurately in the 1950s, this chapter suggests that while bioethics was not simply another antiauthoritarian impulse that surfaced in the 1960s, it was, nevertheless, a complex participant in the cultural politics of that chaotic decade. It was a phenomenon that confronted the more self-interested institutional values of medicine and science while simultaneously recreating the legitimacy that ensured the longevity of those values. (ibid.)

For instance, Mary Warnock, key figure and almost synonymous with bioethics in the UK (Jasanoff, 2005), believed that ethics committees should provide a form of 'corporate decision-making' serving the twofold aims of such an external oversight: being concerned with legitimating research and medical practices and by simultaneously ensuring public accountability (Wilson, 2011). In 1970, the philosophers Andre Helleger and Sargent Shriver coined the term 'bioethics' to name a new Institute for the Study of Human Reproduction and Bioethics at Georgetown University in the US (a private Jesuit institution in Washington DC, The Kennedy Institute for Ethics), and one that is still widely recognized today (Martin & Ach, 2002; Wilson, 2011). To Helleger and Shriver, bioethics likewise should be an external examination of biomedicine by people outside its professional boundaries (Cooter, 2004).

This particular type of oversight – regularly referred to as 'external' oversight in many sociological and historical accounts – has consolidated itself as an intermediary primarily in the form of various types of commissions, including: national and state commissions; or local and international non-governmental committees of professional associations; or those within universities; or in the form of the establishment of their own departments or institutes.[4] Associated with these particular forms of oversight mechanisms, Wilson pointed to the shift in the location and exercise of biopower:

> (…) in regulatory commissions, national and international committees, and in the public discussion of professional practices, we have 'witnessed a bioethical encirclement of biomedical science and clinical practice' […]. And this, as Salter argues, represents a fundamental shift in the location and exercise of biopower: with new actors determining the development of policies and biomedical technologies that, in turn, play a crucial role in governing the health of individuals and populations. (Wilson, 2011: 122)

In this sense, it will remain to be shown that it is not so much an 'external' oversight mechanism, but rather a shift in the exercise of biopower through the integration of new actors into the biomedical field and profession (especially when it comes to new and emerging biotechnologies).

In addition to the predominant narrative of bioethics as an 'external' oversight of biomedical practices (i.e., as an intermediary between the will of the people and that of scientists to address controversial issues related to new biotechnologies), there are a number of other such

[4] I will return to these particular institutional places and forms of bioethics, especially in Chapter 3; when it comes to the particular committees of this study, see Chapter 5.

narratives. For instance, Daniel Callahan one of the co-founders of the Hastings Centre in the US, the world's first bioethics research institute, defined bioethics and its tasks in the very early days as follows:

> (…) a range of areas which might be described by others as 'medical ethics', 'clinical ethics', 'research ethics', and 'biomedical ethics.' While there might be arguments about the overlap of topics covered in these terms, they all conform to Daniel Callahan's definition: 'the application of ethical theory to the dilemmas raised by the practice of modern medicine, especially those problems raised by the applications of new technologies'. (Hedgecoe, 2004: 122)

Obviously, Callahan attributes bioethics specifically to biomedicine[5] and in particular, to the problems raised by new (bio)technologies. This is quite illuminating because it very much illustrates that bioethics specifies its objects by assigning them to those biotechnologies to which the emergence and ethical controversiality of these very objects are bound (Gehring, 2006: 135).[6]

Similarly, to the narrative of declining trust in a solely self-regulating medical community, an increasing scepticism towards political institutions and their decision-making processes has arisen, which is predominantly the case for the political climate in the United States. Hence, bioethics as a new type of oversight of science and medicine rapidly became the norm in regulatory commissions and public debate, and bioethicists positioned themselves as adequate intermediaries to represent both: the interests of the public and the interests of science, in the form of legitimizing research practices. Or as John Evans, a sociologist, has succinctly put it: "(…) mediators between the will of the people and the scientists (…)" (Evans, 2002: 92). Evans would describe this particular jurisdictional area (or task-spaces) of bioethics as public policy bioethics. However, there are some problems involved with this intermediary position that bioethics has claimed to fulfil, which can be traced back to the particular methodological basis of bioethics and its argumentative reasoning, including principlism and consensus-making, to which I will return in the upcoming chapter (3), as well as in my empirical analysis (6).

It is a rather complex but also a highly extraordinary dynamic in which bioethics has emerged and still continues to develop. One reason why (as one quickly realizes when reading the literature on the history of bioethics) the narratives and perspectives towards this new field will vary, depending on which accounts one finds. It is therefore quite revealing to read alternately reports written by bioethicists themselves as well as reports that originated outside the community. In this way, discrepancies between the self-perceived roles and tasks and those assigned from outside also become visible. Roger Cooter has noticed that most of the historical accounts have been written by bioethicists themselves (Cooter, 2000), which some have called "origin myth" narratives because those are characterised by a kind of celebratory tone that presents bioethics as the oppositional critics of the biomedical establishment, and bioethicists as challenging the "techno-speak" of medical and scientific academics and preserving the interests of patients (e.g. Jonsen, 2003; Wilson, 2011: 122).

[5] A notion to which I will return in chapter 4.

[6] I will come back to these aspects of bioethics later in the course of this work.

However, most of those historical accounts on bioethics, or as Cooter has labelled them "versions of the bioethicists tale", which are mainly written by bioethicists themselves, can also be read as "(…) a strategy in the historical legitimizing of bioethics and bioethicists" (Cooter, 2010: 664). These narratives have been challenged from different sites with different arguments: some critiques attacked the way how bioethical decision-making has come into being, classifying it as a reductionist principles method (Evans, 2000; Wilson, 2011). While others have criticized bioethics in and of itself from the angle that it serves to isolate biomedicine and science from threatening questions about new technologies and treatments through an increasingly bureaucratic process, instead of challenging biomedicine and acting on behalf of patients (Evans, 2000, 2002; Rosenberg, 1999).

Taken together, this means that it depends heavily on which accounts someone looks at. There are, for instance, (critical) physicians' writings who in fact have been also involved in bioethical work, either in clinical ethics boards or other ethics commissions; or, as already mentioned-above, accounts of theologians and philosophers, sometimes legal scholars who were mainly involved in establishing this new profession in form of new independent research centres (such as the Hastings Center; or academic institutions, such as the Kennedy Institute for Ethics of Georgetown University in the US); or governmental ethics committees, which are often referred to as public policy bioethics, such as the one established in 1982 in the UK for human fertilization and embryology authority (HFEA) chaired back then by Mary Warnock.

Because many of these stories present the rise of bioethics as merely a response to moral dilemmas and scandals raised by the advances of biotechnologies, they seem to disregard somehow the social, political, economic and also cultural circumstances in which the whole development of bioethics and its institutionalization has to be situated (Cooter, 2010). The reason why a critical scholarship has arisen with an interest in the emergence of bioethics and its respective developing institutions, such as ethics committees, which rather stand out with a more challenging analytical inquiry that asks for "(…) the broad assumptions and mechanisms that underpinned the emergence and growth of bioethics in particular times and places" (Wilson, 2011: 123). Or Ashcroft posed the smart question: "(…) if bioethics is the answer, *what was the question*?" (Ashcroft, 2004: 158).[7]

Those broader inquiries, as Wilson has pointed out, aim at investigating the underlying interests that bioethics tried, or is even currently trying to serve, as well as identifying and understanding the various parties that have benefited from the development of particular answers that bioethics produces. Anyone who wants to understand the bioethical discourse must ask about the desire it is capable of arousing and whether it is actually able to satisfy (Gehring, 2006). Or Hedgecoe, for instance, has challenged the assumption that *research scandals* were the main driver for the emergence of bioethics in form of the Research Ethics Committees (RECs) in the UK. Following Stark, who has called this the "critical event model", which is similar to the "moral panic" view of the rise of the RECs, the author questions the simple fact that the occurrence of a (research) scandal functions as an explanation for the development of bioethics or its institutions (Hedgecoe, 2009: 332). Instead, Hedgecoe suggests that one has to research the

[7] I will revisit this question in particular at the end of the thesis.

conditions and roles of different institutions and actors involved in the development of research ethics or bioethics in more empirical detail.
For example, in the case of the UK and the prominent role that the National Health Service (NHS) played in the development of these RECs:

> UK Research Ethics Committees originated within the National Health Service (NHS), and to examine their development without taking due account of that context, is to fail to provide a full explanation for how these bodies developed in the way they did (…).
> A key problem with the critical events model, with its focus on individuals, whistle-blowers and scandals, and its avoidance of context and continuity in ethical thinking, is that it is exactly the approach offered by bioethicists to explain developments in this area, and as such leads to histories that mirror, rather than examine, bioethical thinking. (Hedgecoe, 2009: 333)

We can thus note, as Evans has rightly pointed out in his analyses of (public) bioethics commissions in the US, that the (bio)medical profession and bioethicists never have had serious competition among each other or were fundamentally questioned by bioethics. In this regard, he follows the historian Charles Rosenberg, who stated:

> (…) bioethics not only questioned authority; it has in the past quarter-century helped constitute and legitimate it. As a condition of its acceptance, bioethics has taken up residence in the belly of the medical whale; although thinking of itself as still autonomous, the bioethics enterprise has developed a complex and symbiotic relationship with this host organism. Bioethics is no longer (if it ever was) a free-floating, oppositional, and socially critical reform movement. (Rosenberg, 1999: 38)

I situate my analysis within this kind of critical analytical inquiry by investigating the ethical accounts produced by two specific actors within their historical as well as organisational contexts: the two ethics committees of the ESHRE and the ASRM. These are quite different in their status and scope compared to national or public bioethics commissions because they are integrated into the professional sphere itself, which constitutes an interesting case worthwhile to scrutinize. In this context, the main question is what kind of governance these ethics committees exercise and at what levels. Therefore, the question is more directed at this particular kind of 'self-regulation' that they engage in and how they do this by navigating between the different interests of patients, professionals and society (different publics) as a whole. An example of this kind of vision can be seen in the mission statement of the EHSRE Ethics Committee: "The mission of the ESHRE Ethics Committee is to examine ethically relevant issues related to reproductive medicine and reproductive science with a (potential) impact on patients, professionals and society as a whole" (ESHRE Ethics Committee, 2022-2024).[8] For my work, the question of whether bioethics is something that genuinely takes place outside the (bio)medical community or is still 'inside' the community is particularly relevant, which actually folds into the question of *who is the bioethicist*, in the sense of who is the *authorized speaker in this discourse*. And consequently, who has the right and appropriate knowledge and expertise to discuss and govern ethically difficult or controversial questions raised by biomedicine and biotechnology, all of which leads into my next section.

[8] See: https://www.eshre.eu/Home/Committees/Ethics-Committee (accessed on 3rd June 2023).

2.2 The Ethicist – *insider or outsider* – who is the authorized speaker?

Let me start this section with an anecdote. At the beginning of my research, while attending an ESHRE conference, I had ample opportunities to speak with several professionals and ESHRE members. These conversations included an ethicist (a trained philosopher and, at the time, an important person on the ESHRE Ethics Committee) and a gynaecologist who attended the conference as an ESHRE member but not as part of the ethics group. After learning that I was doing a PhD in STS, the first one – the philosopher – stressed during our conversation that it would be really important for young scientists like me to be part of such ethics committees because of their valuable expertise on science and technology. It felt a bit like a proposal, or actually more like an assumption that this was going to be my plan, which constituted an interesting experience. I will revisit this story in particular at the end of my thesis and make some assertions about what it might tell us in terms of STS and its potential for bioethics.
On another occasion, the second one – the doctor – asked me if I wanted to work on an ethics committee after I told him what I was doing and what my thesis was about, an offer which I declined. I got a strange smile, but the person was quite satisfied with my answer, because he revealed that he is not completely convinced about the work of (bio)ethics committees, because there are many people involved and working there who, in his opinion, have no idea about the practical issues. The discussion continued with the person telling me that medicine should be de-ideologized, de-politicized and de-dogmatized. I responded by asking which people the doctor would like to see on such a commission, or at least who should be responsible for thinking about ethical issues related to reproductive technologies – only doctors? He emphasised the role of patients, i.e. the people or women concerned. The point of these stories is that they illustrate quite well who may or should speak out in this particular bioethics discourse.
Especially the people who started to describe themselves as (bio)ethicists, indeed embody this new historical figure of *the ethicist,* or the secular (bio)ethical expert, as Petra Gehring (2006) put it.[9] My anecdotes very much corresponds with the prototypical roles of speaker(s) that Gehring identified in the bioethics discourse: *the ethicist* as the main figure with a moderator role, and with some distance from *the scientific-technical expert* (including medical doctors) and *the public*; whereby the latter is just present in form of persons concerned (Gehring, 2006). According to Gehring, there are actually no other spokesperson roles foreseen in the bioethics discourse, which means that there is no room for a legitimate observer position, which is quite congruent with my anecdote above. Because the reaction I got – more or less twice – was: who would write a paper (even a doctoral thesis) on bioethics if they do not plan to work as one?
However, the question 'who is the bioethics expert?' or, in other words, these prototypical spokesperson roles in this bioethics discourse also correlate with another characteristic of this new bioethics profession: its *interdisciplinarity* and *heterogeneity*.
Thus, the question of *what are the actual tasks and aims of bioethicists* will vary too, depending on which site one looks as previously mentioned: e.g. clinical settings, professional- or patient

[9] Of course, there are also critical debates by historians and sociologists or STS scholars, to whom I also refer here, but these are rather outside the bioethics discourse itself.

organisations, government commissions, ethics institutes and boards within academia. Or even industrial settings such as biotechnology companies that run sometimes their own bioethics advisory boards, or hire and contract individual ethicists for overseeing and evaluating their research trials, such as drug tests (Elliott, 2018). Thus, the question arises whether bioethics embodies an attempt to answer ethical and moral questions from within the profession, or rather from the outside and thus serve as a kind of critical corrective of the medical profession and its formerly almost exclusively self-regulating endeavour (Hippocratic oath) and for what purposes it does so. However, this is rather an empirical question, which can also vary depending on which site one looks at.[10]

Stephen Toulmin, for instance, stated that (bio)medicine in a way saved the life of ethics during the time span from 1960 to 1980, because it provided a fertile playground for moral philosophers to apply their expertise and knowledge, starting with practical reasoning in medical matters along particular cases that have given back some seriousness and human relevance to the philosophy of ethics (Toulmin, 1982). However, according to Cooter, the whole enterprise of bioethics "(…) did much more than save the life of philosophy departments; it did as much or more for the medical establishment as a whole" (Cooter, 2010: 666).

As I have described earlier, there is a common narrative that bioethics emerged at a time when a multitude of *research scandals*, especially in the US, came to light as well as puzzling *moral dilemmas* raised by new medical technologies, such as organ transplantation, life-prolonging measures, artificial hearts, genetic engineering, and in-vitro fertilization (Elliott, 2018). The moral dilemmas associated with these new medical technologies put additional pressure on the medical profession and have produced an ever-growing distrust in them. This narrative is more or less commonly shared among scholars; however, the role of the 'scandal' as a legitimizing narrative of the bioethics profession has also been questioned by critical scholars as I have emphasized above. Whether certain incidents of scientific misconduct have actually led to this ethics force, or whether there have been some preconditions within the medical system and its management itself that led to these significant transformations is a much-debated question among critical analysts of bioethics.

Depending on who is telling a story about the emergence of bioethics, different accents and nuances become visible. For instance, the afore-mentioned Daniel Callahan, a philosopher and leading figure in the development of bioethics has described the main strains for founding such a Center and the development of bioethics as follows:

> The Center [the Hastings Center] arose from a confluence of three social currents: (1) the increased public scrutiny of medicine and its practices, (2) the concern about moral problems being generated by technologic developments, and (3) the desire of one of its founders (Callahan) to make use of his philosophical training in a more applied way. (Callahan, 2012: 1)

Callahan, who was also Director of the Hastings Center from 1969 (its founding year) to 1983; past president from 1984 to 1996 and from then onwards president emeritus until 2019 of the

[10] Needless to say, that this particular conceptualization of critique is intriguing, in the sense that it assumes to be possible to carry it out exclusively from the outsight, rather than from within, which turns out not to be straight forward in the case of bioethics, or maybe also in general.

Center, stated that concerns about ethics characteristically emerge when serious political, scientific, and cultural changes are afoot:

> That was exactly the case with the emergence of bioethics. Prior to the 1960s or so, medical ethics was mainly in the hands of physicians. It had scarcely changed from the ancient Hippocratic tradition and focused almost exclusively on the welfare of patients and medical professionalism. (Callahan, 2015)[11]

What we can observe from these statements from a so-called proven bioethicist is indeed this rather celebratory imagination of bioethics being the critical voice of the biomedical and biotechnological enterprise. In this context, Carl Elliott, a philosopher who is fairly critical of bioethics, has pointed to the increasing number of bioethicists acting as advisors for the biotechnology industry, or to the role of commercial institutional review boards (IRBs) in the US and their impact on bioethics as a supposedly critical enterprise:

> To some outsiders, it appeared that bioethics had been co-opted by the very institutions it was intended to study. Many observers agreed with sociologist Jonathan Imber when he called bioethics "the public relations division of modern medicine" (…). Ken De Ville, an attorney and historian of medicine at East Carolina University, wonders (…) "If ethicists are transformed into a bunch of corporate shills who exist only to serve the machine," he asks, "where is the honor in taking part?" Of course, De Ville's comment presumes that there is a distinction between honor and serving the machine. Once the very discipline of bioethics is itself a part of the machine, service is an honor. Laurie Zoloth, the former president of the American Society for Bioethics and Humanities, has written that the real temptations of industry associations are not financial but in the honor and status of corporate consultancies. If she is right and advising a corporation is an honor, then bioethicists have already made the shift from outsider to insider, from critic of the machine to loyal servants. (Elliott, 2018: 140, 147)

This statement firstly provides a glimpse into the important role that the pharmaceutical industry is increasingly playing in the domain of biomedicine and secondly, to the extent of pharmaceutical-funded bioethics and other forms of industry-related bioethics. The resulting dynamic of being inside or outside the machinery, and what this means for the bioethics profession, its discourse and its tasks, is a pressing issue. The relationships between research, industry and governments, which indeed have become an intricate ethical bank (Franklin, 2019), can also be observed when attending these scientific congresses. In particular, the exhibition halls of such scientific societies, where the major players – the pharmaceutical industry and biotechnology companies, as the new and second major player in the field – present and promote their drugs and new technologies. Here it becomes clear how deeply the science of reproductive medicine and its practices are intertwined with industry due to funding and mutual corporations and dependencies. As Elliot points out:

> Bioethicists have gained recognition largely by carving out roles as trusted advisers. But embracing the role of trusted advisers means foregoing other potential roles, such as that of the critic. It means giving up on pressuring institutions from the outside, in the manner of investigative reporters. As bioethicists seek to become trusted advisers, rather than gadflies or watchdogs, it will not be surprising if they slowly come to resemble the people they are trusted to advise. And when that happens, moral compromise will be unnecessary, because there will be little left to compromise. (Elliott, 2018: 147)

[11] See: https://www.thehastingscenter.org/briefingbook/bioethics-and-policy-a-history/ (accessed on 11th February 2019).

Likewise, Charis Thompson, an important sociologist of science, draws our attention exactly to the financial and infrastructural embeddedness of IVF clinics into the pharmaceutical cosmos, when problematizing why most IVF clinics choose superovulated IVF cycles rather than for "natural cycles" (Thompson, 2005). The latter means a woman who undergoes an in-vitro fertilization without taking hormonal drugs, which are supposed to speed up to make several eggs mature at once. The more 'natural' procedure implies that a woman's natural cycle has to be monitored and IVF has to be reconciled with it. As a consequence, natural-cycle IVF is more stressful for the clinic's staff and the treating physician in particular because it is more likely to lose or damage the single egg during retrieval. And further:

> If every clinic moved from superovulated cycles to one or another form of natural cycles, these companies would lose a tremendous amount of current income, and the field itself would lose a major underwriter. While possible, this would clearly take a substantial reorganization of the epistemology, technique, and funding of the speciality. (Thompson, 2005: 98)

Despite this, big pharmaceutical companies (such as Merck KGaA or Merck & Co., Inc. and many more) underwrite the annual meetings of the scientific societies on which my study is based, too, because they provide the vital drugs for reproductive medicine and thus, are major sponsors.[12] These complex financial and infrastructural issues are not the focus of my study, but such insights are important to recognize and are intended to show the extent to which bioethics is interwoven between corporate interests and a socio-political and normative project of practical decision-making; especially in relation to biotechnologies and the moral issues they raise and this is particularly relevant in the face of moral pluralism in democratic societies.
However, the particular controversial nature of ARTs is primarily owed to their potential of unfolding biological novelties (such as IVF embryos) and related therewith, scientific, ethical and social uncertainties and implications (such as new forms of understanding life) that are connected with these technologies (Jasanoff & Metzler, 2020). This means the controversiality results exactly from the technology itself, which Gehring has aptly described as follows: "The final >>meaning<<, namely the product, turns the techniques into what is being disputed: the >>technology<<" (Gehring, 2006: 135; translated). To these aspects, including bioethical tasks as well as how objects are made and transformed within the bioethics discourse, I will return in my empirical analysis (particularly in the Chapters 6 & 7). And, in how far bioethicists are insiders or outsiders of the biomedical profession, or if they are 'public intellectuals', or rather 'loyal servants' of companies and governments remains an empirical question and the answers might be different at diverse places, regions and times.

[12] At the time when Thompson wrote her book *"Making parents. The ontological choreography of reproductive technologies"* in 2005, she considered Serono and Organon as the two largest manufacturers of fertility drugs for the U.S. market; since then, Serono with its headquarter in Geneva was sold in 2006 to the German Merck KGaA for around 16 billion francs; and in 2007 Organon likewise merged into the US pharma company Merck & Co., Inc., which is, including Pfizer, Roche, Novartis, one of the biggest drug manufacturer worldwide with a revenue of approx. 40 billion US dollars per year. See: https://www.forbes.com/global2000/list/#search:merck (accessed on 11th September 2019).

Chapter 3: The institutionalization of bioethics and its discourse

Having addressed the question of 'Who is the authorized spokesperson?', as well as questions about the historical emergence of a 'new' bioethics profession and, in particular, the dominant narratives associated with that emergence, I will now turn to another set of questions closely related to the previous ones. I will focus more on the particular ways of speaking and the spaces in which biomedical questions and technology are made into bioethical questions in the first place. Again, I will refer to relevant literature that deals with diverse aspects of the historical emergence and development of bioethics, but which also discusses the important issue of whether bioethics actually represents a discipline of its own, a sub-discipline of medicine, or of philosophy, a separate field, or maybe a new profession with its own expertise, special knowledge and discourse and, above all, its own kind of argumentation. The latter aspects, for example, the constitution of a 'new' profession with its own discourse (and own language), are of particular interest to my research and will therefore be negotiated along the following aspects in this chapter: First, my analysis draws on Foucault's understanding of discourse, so I will discuss some crucial reference points relevant to my case study. Using key literature, in a second step, I will outline what has been called a 'common' approach in bioethical decision-making: principlism, which is an argumentative approach that has been able to produce a specific discourse around biomedical issues and biotechnologies. In a third step, the way in which this discourse is related to the specific institutionalization of bioethics is examined, taking into account the specific spaces and forms of consolidation of the bioethical discourse.

3.1 'Historical' discourse and normativity, or: how to analyze power dynamics?

> Truth is of this world; in this world, it is produced due to manifold constraints, it has regulating power effects. Every society has its own order of truth, its "general politics" of truth: i.e. it accepts certain discourses which it makes function as a true discourse. (Foucault, 1978: 51; translated by the author)

The term 'discourse' always has been used as an everyday concept, and as a buzzword that has long been in vogue in the social sciences, but it also has a long and highly branched history in theorizing (Gehring, 2006). In Habermas' theory of public discourse, for instance, it is the course of a speech, the process of a negotiation of individual claims to validity of the individual actors. In the further course of his work, he then developed a so-called discourse ethics that claims universal validity because it formulates concrete discursive rules (i.e. it is a normative ethical theory, which should create an ideal situation of communication, in a way) to which all participants in a discourse are subject (Ott, 2021). This also means that the 'observer' perspective is eliminated, so to speak, and that one can only enter the discourse as a participant.

Discourse in a Foucauldian sense, on the contrary, does not mean the course of a speech, this is to say the unfolding of a subject; it instead describes the order and arrangement ('Anordnung'), the framework, the normality of speaking (Foucault, 1981; Gehring, 2006). The concept of *historical discourse* points towards the way(s) of speaking, the set of things that are said. In my work, I follow this understanding, and there are three particular features of

Foucault's concept of 'historical' discourse that I would like to highlight here: 1) he has a strict methodological program associated with his theory (described as the "archaeology of knowledge"(1969); 2) with this method, an observer's perspective/position is possible within a discourse and 3) discourse(s) are always mediated with power relations, that is, every speech action is in some way strategic action and therefore, one must look at micro-practices of power. I will return to the question of normativity, or to the accusation of the lack of a normative stance in his discourse-theoretical concept in a moment. And Foucault's observer position I would coin in an ANT-understanding as "a very crude method to learn from the actors without imposing on them an a priori definition of their world-building capacities" (Latour, 1999: 20). And it is up to the observer or analyst to follow exactly these associations that the actor-network is drawing.

Also relevant and important is the focus on scientific discourses or those discourses that are on the way to *epistemologization*. This concentration on the discursive potency of the humanities is Foucault's trademark, in a way. It is hard to separate it from the solid thesis expressed by the author in the very end of the "archaeology of knowledge" (1969), namely, the thesis of the constant epistemologization of culture:

> The orientation towards the episteme has been the only one to be explored so far. The reason for this is that, because of a gradient that no doubt characterizes our cultures, discursive formations are constantly becoming epistemologized. It is by questioning the sciences, their history, their strange unity, their dispersion, and their ruptures, that the domain of positivities was able to appear; it is in the interstice of scientific discourses that we were able to grasp the play of discursive formations. (Foucault, 1972: 195)

In this sense, it is advisable not to take at face value the idea that discussing biomedical matters, such as controversial biotechnologies, is only possible in (bio)ethical terms and language(s). However, it is indeed the dominant and powerful way of thinking about controversial (ethical) issues in biomedicine and, in particular, when it comes to reproductive technologies.

This points precisely to a very specific type of discourse that emerged and prevailed for specific reasons and at a specific time in history. As Wilson put it in accordance with Cooter: "(…) 'bioethical' aspects of particular practices and objects were not self-evident, but were the product of specific socio-political contexts and professional agendas in the late twentieth century" (Cooter, 2000; Wilson, 2011). As noted above, the emergence of bioethics has often been seen as being in tension with biomedical self-regulation and the increasing call for new regulatory regimes. That is, the long-standing supremacy of physicians in self-regulating their own specialty was challenged at a certain point in history, when research scandals – so the common narrative – increasingly came to light (especially in the United States).

An example of one of these scandals is found in Maurice Pappworth's 1967 book "*Human Guinea Pigs"*, which reported over two hundred cases of inhuman research abuse without the subjects' knowledge (Elliott, 2018). However, as noted above, some scholars have rightly criticized this 'scandal narrative' as the main driving force behind the emergence of bioethics and its institutions and have viewed it as a rather problematic narrative and argued for a closer look at systemic changes within particular institutions (Hedgecoe, 2020). As context, however, it cannot be entirely dismissed, as we have seen, it is precisely this narrative that has helped

bioethicists themselves to justify their legitimacy and to present themselves as a kind of corrective and control mechanism for biomedical research and practice. Stevens, for instance, concluded:

> By the mid-1970s, bioethics was functioning as midwife to technologies and to a medical research community in need of broad social acceptance. The history of bioethics, considered within the larger narrative of 1960s protest culture, suggests that the movement from the sixties to the seventies was a shift from critique to management. The cultural politics of bioethics exemplifies an important phenomenon in recent American history, namely the ebbing of the protest culture of the 1960s. (Stevens, 2000: xiv)

Stevens, like many other critical reviewers of the history of bioethics, portrays bioethics during this period of its institutionalization as a vehicle of the medical establishment and its emerging technologies, and thus of biomedical political interests, to provide a basis for public acceptance. Moreover, how this shift from critique to management relates to the understanding of bioethics as a governance practice is also crucial.

The idea of coproduction

My study, however, does not claim to be an archaeological description in a strict Foucauldian sense but rather makes use of his rich toolbox, which becomes further populated with a number of relevant STS concepts (see Part B & especially Chapter 5), which, in turn, have attempted to take his theory and methodology further, or even to modify it. In other words: I am Doing Foucault.[13] Thus, it is now necessary to revisit the question of the supposedly missing normative element in Foucault's discourse analysis, because it is a perfectly legitimate question of how power critique is possible without any kind of normative position (Stögner & Colligs, 2022).

> (...) to understand a certain vision of normativity as an essential point, an ingredient in a critical theory. (...) But then, of course, the great debate began, the >debate< with Foucault, and here the question arose in my mind whether a critique of power is possible without some kind of normative standpoint. If one criticizes power, in whose name does one actually criticize it? The Foucauldian answer to this would be that one does not need a normative standpoint, but that one needs to focus on micro-practices of power that would allow and enable resistance. (Stögner & Colligs, 2022: 68; translated by the author)[14]

Even though I would not necessarily subscribe to this criticism of Foucault, it is still important to bear it in mind. However, my work also borrows of his ideas of 'genealogy', where he located the question of power in and of discursive formations. *Genealogy* is thus not the search for actual origins, nor the narration of linear developments, but the reconstruction of historical power relations and fields of tension under which what is commonly understood as 'knowledge' or 'truth' has grown in discourses, categories that then themselves also exercise and distribute power (Foucault, 1974). Against this backdrop, I must situate my Foucauldian understanding

[13] See: https://www.rsozblog.de/diszipliniert-foucault/ (accessed on 13th February 2023). *Doing Foucault* means especially to look at certain (sociotechnical) phenomena in a particular – Foucauldian – way, which I try to demonstrate in this thesis.

[14] Interview with Seyla Benhabib about the foundations of a feminist critical theory: "Das Partikulare im Namen des Universellen mobilisieren" (2022).

outlined above in the tradition of Sheila Jasanoff and other STS scholars, who investigate the co-production of knowledge and social order, which is to say looking at the simultaneous process(es) through which modern societies form epistemic and normative understandings of the world that mutually shape each other (Jasanoff, 2004). This idiom aims to scrutinize the manifold "knowledge conflicts within worlds that have already been demarcated into the natural and the social" (ibid.), since:

> For Jasanoff, it is not the purification of nature and society that is the key constitutional move of modernity. Rather, it is the continual production and reproduction of epistemic, material and normative hybrids that are constitutive of worlds that make sense and hold together. (Willems, 2014: 41)

Willems, who interviewed Jasanoff in 2014, nicely illustrated the two different emphases or accents that exist within STS (which are not mutually exclusive) by using Dolly, the 1996 Scottish cloned sheep, as an example:

> Latour would focus on the ontological aspects: making visible the actor network that stabilizes Dolly as a technoscientific object, separating it from Dolly as an object of political or ethical deliberation. Jasanoff, on the other hand, would emphasize precisely those latter dimensions, using the normative discourses on Dolly as a vehicle for exploring why particular sociotechnical constellations take the forms they do. From this perspective, the birth of Dolly is a disruptive event that revealed a range of already existing frames within which social actors think and act. Focusing on the effects of such transformative events can bring more clearly into view salient differences between the political cultures of different countries and societies. (ibid.: 42)

In my research, I also aim to address precisely the political and normative dimensions within epistemological discourse practices by examining the wide range of ethical statements, guidelines, conference contributions and discussions produced by both actors: the ASRM and ESHRE Ethics Committees, which are situated in different socio-geographical and cultural environments. Comparing such ethical statements and other materials from two institutional actors allows me to examine, how 'plurality' (i.e., discursive bifurcations, different strategies, concepts, and issues related to biomedical issues, and in my case more precisely to reproductive technology) is performed differently and how this is then justified.
Additionally, through these documents, a huge network of relations between different actors becomes visible. Therefore, it is important to study the intra-professional dynamics that are present in this discursive formation, where particular bioethical questions become enacted in the first place and negotiated in the face of value pluralism without falling victim to relativism. Jasanoff, for instance, has written in her introductory essay of the "States of Knowledge" (2004):

> The co-production idiom, embracing as it does the constitutive as well as the interactional lines of thought, may offer at least a partial release from these dilemmas. It provides, following Latour and Foucault's later work, the possibility of seeing certain "hegemonic" forces not as given but as the (co-)products of contingent interactions and practices. These insights may, in turn, open up new opportunities for explanation, critique and social action. (Jasanoff, 2004: 36)

The question of who is authorized to speak ('truth') in a particular discourse formation is strongly associated, or coproduced with the specific rules of speaking that are established in

that particular bioethical discourse, but also with the spaces where these rules of speaking become articulated. This means that, within a discourse, there are some statements that are foreseen and possible, and others that are not, in the sense of conventions. Such hegemonic conventions of speaking might occur in different kinds of institutions (such as clinics, judicial systems, or, in my case, the ethics committees of scientific organisations) or within the bioethical discourse in general. In this understanding, the discourse as an assemblage of implicit rules constitutes a phenomenon of power because it exercises pressure and constraints, because it produces hegemonic modes of ordering.

Discourses can be understood *as practices that systematically form the objects of which they speak,* which leads us to the question of which kinds of contexts or weavings get construed in which specific ways; where different things (such as human actors, biological entities, technologies, procedures and therapies, and moral values and narratives) become specifically ordered and located in space and time; and along with that, how particular issues emerge. Furthermore, discourses are not uniform practices, but rather exhibit a range of bifurcations – in this context Foucault noted:

> If I suspended all reference to the speaking subject, it was not to discover laws of construction or forms that could be applied in the same way by all speaking subjects, nor was it to give voice to the great universal discourse that is common to all men [sic!] at a particular period. On the contrary, my aim was to show what the differences consisted of, how it was possible for men [sic!], within the same discursive practice, to speak of different objects, to have contrary opinions, and to make contradictory choices; my aim was also to show in what way discursive practices were distinguished from one another; in short, I wanted not to exclude the problem of the subject, but to define the positions and functions that the subject could occupy in the diversity of discourse. (Foucault, 1972: 200)

To sum up at this point, the ways of speaking are coproduced with the spaces in which these rules speaking are performed. This means that the *spaces* and *ways of speaking* in which *legitimate arguments* and *justifications* about *objects* are produced are crucial elements when analyzing the bioethics discourse. But also the objects themselves are also not given because how they are made and how they become certain *issues in the discourse*, is another level to consider in the analysis of bioethical discourse. Taking all this together, including the historical context(s) mentioned-above has led to the consolidation of bioethics, its profession, and its discourse into specific fora, such as national (state) commissions, or RECs in the UK, or IRBs in the US, or independent ethics committees within specific institutions (such as those in this study, or within universities or hospitals) or in the form of the establishment of separate departments and institutes. In addition, most of these committees produce very specific types of reports (e.g., opinion papers, recommendations, guidelines etc.) that, in a sense, systematize and articulate these very rules of speaking, thinking and reasoning. The type of reports and arguments that are produced also very likely correspond to the type of committee that produces them. However, this entire process constitutes a moment of effective co-production: The rules of deliberation (including legitimate arguments and justifications), their concepts, objects, and the intuitional spaces in which these are enacted, shaped, and articulated are co-produced in specific ways; ways that my study aims to map – although without claiming to do so exhaustively. It is the very nature of such a case study that it can only present an expression

of the phenomenon it studies, but it certainly provides essential insights into the workings of this discourse. Some of the findings may very well be generalized, especially the specific way(s) of speaking (so how it is argued and reasoned within the bioethics discourse) and how medical practices and technologies in the field of reproductive medicine become justified.

3.2 A common way of speaking in bioethical decision-making: The 'principle-based approach' as a form of applied ethics?

After outlining the theoretical perspective, I will now turn my attention to another characteristic feature of bioethics: the particular approach to developing ethical arguments. That approach is based on a so-called 'principlism' that follows the well-known four-principle model (respect for autonomy, nonmaleficence, beneficence, and justice) developed by Tom L. Beauchamp (a moral philosopher) and James F. Childress (a theologian, philosopher and medical ethicist). They outlined those four principles in their book "Principles of Biomedical Ethics" first published in 1977 and which is accessible in its 7th edition (from 2013). Despite the criticism and the crisis of the principle-based approach (Evans, 2012), they still represent a very classical approach to ethical decision-making in medicine that is still in use today, as I will show in the analysis that follows (Chapter 6).

As such a classical approach, and as a result of repeated unethical research projects (such as the Tuskegee syphilis experiment) these ethical rules were first formalized by the US National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research in a document known as the *Belmont Report,* which was released on April 18, 1979 and contained three of the four principles: *respect for autonomy*, *beneficence* and *justice*. This US National Commission came into force on July 12, 1974, when the National Research Act (Pub. L. 93-348) was signed into law (Bulger, 2007). For completeness, it should be noted that the fourth principle*, nonmaleficence*, was not included in the Belmont Report, but was elaborated by the founders of the principles in their book, which colloquially means that no harm should be done to a person (either in research or clinical settings).

In a sense, these principles represent a system of abstract knowledge because they perform a particular way of structuring biomedical knowledge. Initially applied mainly in the context of research on human subjects, they have now been extended to more and more areas of bioethical discourse and have now become a standard procedure in biomedical ethics and its decision-making system (from research questions, over questions in the clinic, to resource allocation, to questions about access to treatments, and patient-doctor relationships). In particular, the socio-political context of origin in the United States is not insignificant, but elsewhere these four principles constitute a standard-procedure in bioethical decision-making:

> (1) **respect for autonomy** (a norm of respecting and supporting autonomous decisions), (2) **nonmaleficence** (a norm of avoiding the causation of harm), (3) **beneficence** (a group of norms pertaining to relieving, lessening, or preventing harm and providing benefits and balancing benefits against risks and costs), and (4) **justice** (a group of norms for fairly distributing benefits, risks, and costs). (Beauchamp & Childress, 2013: 13)

Two of them (nonmaleficence and beneficence) have a fairly old history in medical ethics as well as the practice of informed consent, whereas the other two principles (respect for autonomy and justice) were neglected in traditional medical ethics for a long time, according to Beauchamp and Childress. For example, the Belmont Report enshrines the principle of *respect for autonomy* through the *informed consent process* in biomedical research; a "risk-benefit-assessment" should guarantee *beneficence* (i.e., contribution to a person's well-being); and "fair procedures for selecting research subjects to ensure *justice*" (Evans, 2002: 84).

It's most obvious feature, particularly in the US, is to resolve many ethical problems with its seemingly magic bullet: *informed consent* – which is one reason why some scholars have spoken in this regard about a formalization or ritualization of ethics (e.g. Åm, 2019; Evans, 2002; Felt, Bister, Strassnig, & Wagner, 2009). Importantly, the concept of informed consent is not just a central issue on which most of the ethical problems in biomedicine and human experimentation must hang, according to Harvard anaesthetist Henry Beecher, but it is crucial to the reconfiguration of what it is and means to be human (Cooter, 2010: 668). On the ground of the informed consent lies a historically predicated notion of human nature, which prioritizes and celebrates personhood within a particular politico-economic context:

> Personhood displaced alternative more communal discourses – be they those of doctors speaking protectively as a corporate body, or communities as a whole in concern over health care and its provision. Fundamental here is not that the authority of doctors was displaced by the would-be authority of (laity-minded) bioethicists (a fallacy in any case), but rather, as Foucault would have it, the replacement of one 'truth regime' by another – namely, an ethics based on 'the social subject' to one grounded on 'the self'. (Cooter, 2010: 668)

This shift towards autonomy is a discursive one because it signals a new psychological and moral way of "making up people" (ibid.), which reaches far beyond them being merely political or medical. The aspect of informed consent and, in particular, its underlying principle of "autonomy" (respect for persons and their decisions) with which this practice has been legally protected and justified, will be picked up again in more detail in the two empirical chapters that follow (6 & 7).

Furthermore, following the founders of the principles, the four biomedical principles are all equally important and need to be specified and weighed against each other individually. Moral controversies could be seen as conflicts between these differently weighted principles, according to the founders. In addition, the principles were intended to provide a practical, i.e. applied approach to ethical dilemmas in biomedical research; but because they have been increasingly extended to other areas of medical practice, legitimate questions have arisen as to whether they may be applied too rigorously and whether every "dilemma" or ethical problem can be addressed at all by this four-principle approach.

John Evans, a sociologist, has investigated the growth of principlism in bioethical deliberation and decision-making in the 2000s from a sociology of knowledge perspective by focusing in particular on the development of professions. This means he analyzed the growth of principlism along the question: *"(…) why [did] the use of a small set of principles – whichever they may be – become common in bioethics?"* (Evans, 2000: 31), rather than asking if those principles are the 'right' ones, or how they apply in practice. His research is similar to Hurlbut, whose analysis

also rests on the workings of public bioethics in the US (in the context of embryo research debates) and how science and politics are co-constructed at these sites and how they develop and claim authority over public reason. Evans, for instance, said with regard to public bioethics:

> Public bioethical debate is where societal elites – in this case, professionals – debate over what society should do about a problem such as HGE [Human Genetic Engineering]. In the language of social theory, this is the debate in the "lifeworld" that people like Habermas are so concerned about. Of course, in an ideal sense, there is no reason why the public cannot debate the issues without elites. However, given the specialization that has occurred in modern society, people now rely upon experts at least to lay out the various ethical arguments. The purpose of the public bioethical debate among the professionals is to influence the beliefs and values of the public, to come to some modicum of consensus, or in some cases to represent public opinion to policy makers. (Evans, 2002: 34)

He distinguishes two further forms of bioethical debate, which he calls the foundational and clinical: the first is characterised by the question of how debates about bioethical issues are related to broader societal concerns (like systems of ethics or democratic practice); the second specifically addresses the relations and interactions between patients and doctors in the clinical context, or researchers and research participants in a research setting. His main thesis is based on the claim that public bioethical debate (bioethicists, i.e., experts, on national ethics commissions) tends to 'emptying out' democratic debate about so-called *ends*; that it favours instead a discussion – a particular rational debate he calls "formally rational debate(s)" (ibid.) – about means rather than ends, indicating a thinning out of democratic debate, as well as a suppression of a more radical critique about the ends of technology (Ashcroft, 2004).[15]

Evan's analysis of the principle-based approach of bioethics particularly follows Max Weber's theory of the tendency towards rationalization in modernity (with reference to double-entry book keeping to make interactions and structures calculable, or even the discussion of ends and means and commensurability) and Habermas' continuation of Weber's theory by examining how the living world(s) are increasingly rationalized through discourse practices under a capitalist logic. In his analysis, Evans attempts to show the extent to which the public bioethical debate has become an expression of such a rationalized mode of discourse by employing a small set of principles that, in his view, constitutes a system of commensuration and thus reductionism (Evans, 2000).[16]

There are two further main arguments in his analysis that are worth mentioning in this context: *first*, it supports the claim that the development of the *four* principles (and not e.g. 10 or 20 or 30 …) were created to enhance calculability, in the sense of comprehensibility. So that people can comprehend the decisions being made (or which are going to be made in the future) by some ethicists, which is particularly convenient for governmental actors to handle. For this reason, it needed to be a rather simple decision-making system so that it is easier for people to

[15] However, in his later extended and condensed analysis on the *"History and future of bioethics. A sociological view"* from 2012, Evans tries to distinguish between *research bioethics, health-care ethics consultation, public policy bioethics and cultural bioethics* (Evans, 2012), which demonstrates, in a way, the complexities of analysing an emerging profession, but also the potential shifting of discursive formations, which have gone through several stages of changes and crisis in its formation and which is still in progress.

[16] In contrast, he suggests, that a substantively rational debate about ends, which means about what a society should do, is crucial for any democratic society.

follow the argumentations behind those decisions or the particular reasonings. It is also no accident that the four principles were robustly institutionalised by transforming them into legal norms in the US. *Second*, a unique form of argumentation underpins the creation of ethics as its own profession. By referring to Abbott, who developed a sociology of professions, Evans states:

> The dominant view in the study of professions is that they are not defined by the existence of an association, nor by having a specialized degree. Rather, they are defined by having a distinct system of knowledge that they use to solve the problems in their jurisdiction. This system is taught by the elite to the average members of the profession – and the dominant system in bioethics is principlism. (Evans, 2000: 36)

This statement is both coherent and central to Evans's overall analysis, which rests on the argument that principlism as a distinct form of argumentation created its own profession around it. These principles, as mentioned earlier, formed the basis of the Belmont Report and were later set forth in a book by Beauchamp and Childress first in 1977, and provided the initial impetus for institutionalizing the ends of the bioethics debate. Using them, Institutional Review Boards (IRBs) in the US review human subjects research to determine if the research meets these institutionalized ethical foundations and whether it should receive government funding. The involvement of the state – at least in the US – led to, on the one hand, the institutionalization of these principles as ends in-and-of-themselves and, on the other hand, favoured the spread of this specific form of argumentation beyond the issues of human experimentation.

As a number of other biomedical issues (such as reproductive technologies, human genetics, organ transplantation, etc.) emerged, they created pressure for responses from policy makers. Consequently, the 'Principle book' itself led to a tremendous proliferation of this particular bioethical argumentation, namely from a research context to clinical issues to a practice context of doctor-patient relationships:

> According to observers of the profession, this one textbook, more than anything else, "shaped the teaching and practice of biomedical ethics in this country…. [becoming] a standard text in courses and a virtual bible to some practitioners". The ethical framework provided by the book "shapes much of the discussion and debate about particular bioethical issues and policy, whether in the academy, the literature, the public forum or the clinic". The institutionalization of this form of argumentation for human experimentation and increasingly for other problems was so strong that one set of critics would go so far as to begin their essay with the mocking claim that "throughout the land, arising from the throngs of converts to bioethics awareness, there can be heard a mantra '… beneficence … autonomy … justice. (Evans, 2002: 90)[17]

These developments led to a huge jurisdictional expansion of bioethics, namely from the previous exclusive area of medical research to the ethics of medical practice and science in general. In his book, *"Playing God? Human Genetic Engineering and the Rationalization of Public Bioethical Debate"* (2002), Evans also articulated a difference between the bioethics debate and the bioethics profession that is noteworthy in this context: The bioethics debate must be

[17] Evans refers with regard to these critical or even polemic quotes, on the one hand, to an introductory chapter by Edwin R. DuBose et.al In: "A Matter of Principles? Ferment in U.S. Bioethics" (DuBose, Hamel, & O'Connell, 1994), and on the other, to Clouser and Gert "Critique of Principlism" (Clouser & Gert, 1990).

distinguished from the bioethics profession, whose members Evans refers to as bioethicists. Although all who participate in the bioethics debate are popularly identified as bioethicists, it is important for his analysis that only those who use the typical form or argumentation of the profession are considered bioethicists. Members of other professions who participate in these bioethical debates are not bioethicists "unless they use the system of argumentation of the bioethics profession" (Evans, 2002: 34). That is, Evans explicitly ties the emergence or existence of a bioethical profession to the development and use of a particular mode of argumentation, which he in turn distinguishes from a general bioethical debate. And he continues:

> (…) the earliest individuals involved with public bioethical debate, such as Callahan, did not set out to invent a new profession. Their dream was that the public bioethical debate would have representatives from multiple professions, explicitly combining the arguments of the social sciences, theology, philosophy, medicine, and science to solve ethical problems in society. Despite these intentions, a group of people who called themselves bioethicists – rather than theologians, philosophers, or members of any other existing profession – created a distinct form of argumentation for this purpose. (Evans, 2002: 35)

Obviously, principlism is not the only way of doing bioethics, and different philosophical systems, and styles of thought have arisen in different contexts, but according to Hedgecoe, "(…) relatively little change has occurred in the contours, context, style of thought, or ideology of bioethics" (Hedgecoe, 2004: 123). He has similarly pointed out that the very fact that these other approaches appeared as opponents of principlism actually confirmed it as the dominant 'applied ethics model' of doing bioethics, particularly in the US. According to Hedgecoe, although it does not represent all opinions in bioethics, it is the prevailing style in academia, in clinics, and in the presentation of bioethics in the media, and it is indeed a far-reaching discursive formation. As I will show, this is not only an American way of thinking and doing bioethics, but these principles are primarily applied in the ethics committee of the European organization to address ethical concerns in the field of assisted reproductive medicine.

To provide a contrast with Evans, I will draw now from the work of Baker (2002). He is a voice from bioethics itself and contends that bioethics provides a more robust and fertile field for discussing bioethical issues than the thin field that Evans calls *public bioethics*. Specifically, he argues:

> In the spirit of Socrates, bioethicists wander outside of academia. They are found in hospital corridors, in laboratories, and in corporate boardrooms; they discuss, opine, and lecture in churches; they serve as talking heads on television; and they write newspaper columns. They even organize to facilitate healthcare reform […] and to challenge laws promulgated by bioethics commissions […]. Bioethicists continually foster public debate over bioethical issues, and in so doing most bioethicists consider precisely the questions about ends that Evans claims we eschew. (Baker, 2002: 10)

One of the main strengths of Evans' analysis of the bioethics profession, however, was that he clearly pointed to a major aspect of bioethics, namely, the development of its own professional language – a unique way of arguing "rationally" – as he put it and thereby ordering and shaping debates and changing the professional landscape by involving different disciplines, framing questions in specific ways, and offering particular solutions to problems and issues in the field of biomedicine. In his later works, Evans also elaborated somewhat on another important method of bioethics, namely, consensus-making among various committee members, which

also encourages particular forms of deliberation and responses, which I will discuss in more detail later (Chapter 6).

In this context, I might raise the question of how or by what characteristics these ethics committees are classified (e.g., as opposed to a public bioethics committee, which many other STS-related scholars have chosen for their analysis in the context of democratic decision making)? Because they do not consider purely foundational aspects of bioethics (how to debate and for what purposes), nor do they consider exclusively clinical (patient-doctor relationships) or public aspects (desirability of a technology) of bioethics debates, I suggest that this is an empirical question that the following analysis will address by showing that it is a complex interplay of different dimensions that these bioethics committees with their debates try to manage: they move between public interests (needs and concerns of patients and other people concerned), societal interests (economic aspects such as resource allocation, costs, benefits to the whole, equality issues), and especially professional interests (freedom of science and practitioners by considering aspects of research integrity and emphasis on provider autonomy). In what follows, I will take a closer look at exactly the spaces and forms in which this particular discourse has emerged, but under the auspices of its regulatory functions.

3.3 Legitimate spaces and forms of exercising power in the bioethics discourse: Managing the boundaries between science and policy

What makes bioethics unique and applies equally to bioethics in the US as well as bioethics practiced in European countries, such as the UK has been that it was exercised not solely by medical professionals (as it was the case with more traditional medical ethics), but rather by a diverse range of actors, such as scholars, lawyers, philosophers, theologians, social scientists, and sometimes also by patient representatives. This narrative of expansion is a quite common feature of historicizing bioethics: it differentiates it from a previous "self-interested, doctor-driven medical ethics" from "an allegedly lay-driven bioethics" (Cooter, 2010: 664). Although social scientists have occupied a special role within bioethics research, who have not engaged in bioethics directly – at least in the 1980s – but rather criticised the way how 'bioethicists' (at this time primarily philosophers and theologians) practiced bioethics (Chadwick & Wilson, 2018). However, an interesting circumstance is that some of the involved professionals, with their different disciplinary backgrounds, started to call themselves bioethicists instead of representing themselves as representatives of another discipline, such as moral philosopher, lawyers, theologian, or any other.

This is one of the reasons why Evans distinguishes between a bioethics debate and the *bioethicist* as a professional. In his opinion, the latter is more of a self-attribution, which he chose as an analytical entry point. However, in this regard, he uses the notion of *jurisdiction,* which constitutes one of the key dimensions in theories about professions and their development. Abbott, a distinguished sociologist of professions, noted that to adequately understand professions, one must focus on jurisdictions, that is, the areas of work over which occupational groups compete with one another (Abbott, 1988). In the early days of bioethics, there was a particular competition between theologians and philosophers – the parents of

principlism, as Evans calls them – and in particular, between a more universal, secularly oriented theology and a more particularistic approach of Catholic theology or religious ideology. In a sense, this also means that the development of bioethics represents a history of evolving secular ethics that is open to rational discourse independent of any particular tradition (Engelhardt, 1996). Even within philosophy, such a rational knowledge system generates less tension because it provides a common approach (principles) to ethical decision-making that both deontologists and consequentialists or utilitarians can agree on – precisely the reason why Evans describes this approach at its core as a commensurable metric.

Regulatory science

According to Evans, the growth of state commissions, or those which are closely connected to it, at the national level also provided an exceptionally fertile ground for the growth of principlism. This is also an example of bioethics entering into a close relationship with the regulatory state, besides its already close relationships with the pharmaceutical and biotechnological corporations. One effect was simply that bioethics extended its particular system of decision-making (specific reasoning) into more areas because of its "simplicity" and commensurability, thereby expanding its responsibilities (or: jurisdictions). Thus, there has been a general increase in ethics committees at various levels and institutions (universities, clinics, professional associations, other institutions, or separate departments). As Evans notes:

> The "task" of bioethicists is the translation of arguments into what has been set as the commensurable, universal (and numerically limited) ends of society, so that the bureaucratic state or any other formally rational institution, such as a business or a hospital, can make legitimate decisions without directly consulting the public. (Evans, 2002: 92)

Kuczewski, for instance, has stated that contemporary biomedicine is a collective enterprise in which the public has invested heavily and it becomes difficult to differentiate between a private sphere and a public sphere (Kuczewski, 2007). Despite our democratic ideals that everybody has the chance to be free in their choices to pursue their vision of good life, we have to admit that the development of a specific common biomedical infrastructure will shape the styles of lives available to us and the possible paths to fulfilment of happiness respectively (ibid.). Hence, the criteria how to establish such a biomedical infrastructure is at stake, and the logical conclusion to the author is that bioethics must be a public matter by facilitating public deliberation: "Entities such as bioethics commissions assist this process by clarifying policy options and pointing the way to potential consensus solutions that respect the competing values at stake. In this way, bioethics commission can aspire to perform a public service" (ibid.: 84). In this context, the notion of *regulatory science* proves relevant and useful. The term was introduced by Jasanoff in the 1990s in her book "The Fifth Branch: science advisers as policymakers", but she had already spoken of policy-relevant science in an earlier article entitled "Contested boundaries in policy-relevant science" from 1987, where she described the same phenomenon (Jasanoff, 1987). By regulatory science, she describes a particular scientific activity found, for example, in *advisory committees* whose goal is to provide relevant input for

public policy-making. Thus, regulatory science is the body of scientific and technical knowledge that serves regulatory decision-making (Jasanoff, 1994, 2011). This is related to the concept of *expertise*, which describes the transformation of scientific and technical knowledge into expertise, i.e. knowledge that can be used as a basis for policy-making and its decisions. In this context, it is relevant to ask what is the status of 'moral expertise' in form of such ethics commissions and guidelines, as well as to ask about the institutional spaces in which it emerges, its limits, its functions, and the conditions under which it becomes indispensable (Nowotny, 2005).

This kind of knowledge transformation particularly occurs in what Miller and other STS-scholars call boundary or hybrid organisations (Miller, 2001). To what extent the work of such internal ethics committees of international scientific societies can be seen as this kind of regulatory science activity is an interesting question and it depends on what goals they pursue in their ethical negotiations and decisions. But what becomes quite clear from their paper work, however, is that they are attempting to navigate (and define) the various boundaries between research, clinical (doctor-patient), and policy aspects within which they locate the 'ethical' issues of various practices in ART. Therefore, both organizations, with their ethics committees and their particular work (opinion papers), seem to aim in both directions, because they manoeuvre and work their way through this boundary between science and policy. However, this boundary work should be understood as a hybrid space rather than a thin boundary line along which they shift back and forth (Miller, 2001). In this sense, professional associations of this kind can indeed be seen as particular sites where regulatory science is expressed. Jasanoff described this as follows:

> Regulatory science is a term that's used to describe a particular domain of scientific activity: that domain of science which serves regulation in the same way that you can talk about medical science (science that serves medicine) or you can talk about environmental science (science that help us understand the environment). Regulatory science describes a social zone in which a particular kind of knowledge is produced. (Jasanoff, 2011: 11)

The main activities of these particular zones of epistemological knowledge production could be seen in their translational work. In the case of advisory committees, Jasanoff proceeds to explain how regulatory science is dependent and entangled with law, politics and values: "It's important when one says "this is good science" or "this is bad science" to keep in mind that there is a whole infrastructure for regulatory science which is quite different from the science done in laboratory for the purpose of curiosity" (ibid.). Here, she is referring to the US-context, where there is a separate law to regulate the criteria for the behaviour of advisory committees. Jasanoff mentions that such advisory committees must be "balanced", whatever that means exactly, but it certainly means that a regulator cannot simply count on those whom it regards as the best scientists, but must set some criteria (although how one sets such criteria is also noteworthy) that must be met to ensure some kind of balance in membership so that a plurality can be represented. How this is done, for example, in the case of the ethics committees in this study is addressed in more detail in section 6.1.

Moreover, Jasanoff is interested not only in how regulators deal with this particular knowledge or expertise provided by regulatory science (in the form of advisory bodies), but more importantly, in how they deal with uncertainty. This dual thrust is precisely concerned with how values enter into the process of using and evaluating regulatory science, and how data and knowledge are, in turn, reanalysed at different sites, times, and places.[18] The simultaneous process of how epistemic and normative understandings mutually shape each other is what Jasanoff calls co-production, rather than bias or distortion.
On the contrary, I focus on another question, namely whether, and if so, how an ethics committee within a professional society performs this kind of regulatory science activity (in the sense of enacting 'ethical' expertise as a kind of boundary function). Therefore, I am interested in how this is done at these specific places, which could be indeed seen as kinds of hybrid organizations, because they operate exactly between the boundary of science and policy. Jagd, for instance, has also emphasized that different types of organizations may also be seen as devices for designing specific kinds of agreements and compromises (Jagd, 2011).

However, bioethicists and their role – from critical reviewers to trustful advisers – have changed or been emphasized differently over time. This also has to do with the institutions in which bioethicists are embedded (clinics, hospitals, universities, scientific societies, IRBs, national (public) bioethics commissions, or the industry sector, such as biotechnology- or pharmaceutical companies). These different places where bioethics expertise and rules of speaking are produced have an impact on the kinds of arrangements that are reached, such as local and temporary agreements or compromise and clarifications. These are interesting nodes for analysis because one can examine the different ways of reconciling various modes of justification. Therefore, in the following section, I will direct my conceptual gaze more closely on the governance aspects of bioethics, including the particular relationship between bioethics and policy-making.

[18] In her studies, Jasanoff investigated how this is done in court cases.

Chapter 4: Bioethics and governance

In this final section of the conceptual part, I provide a broader discussion of the literature on governance and bioethics that forms the backbone of crucial aspects of the forthcoming analysis. My aim here is to prepare the ground for the analytical chapters that follow, in which I will examine bioethics and its discourse as a tacit mode of governance practice by focusing precisely on the work, and especially the literary productions, of the two internal ethics committees of ESHRE and ASRM.

I start with a brief consideration of the *notion of governance* and then turn to the broader framework in which bioethics is embedded: the sweeping social transformations in – but not limited to – Western medicine in the 20th and 21st centuries, which social scientists refer to as *medicalization*. In light of an increasing shift toward technoscientific biomedicine, some scholars started to speak of a second transformative shift, which they refer to as *biomedicalization*. Therefore, I will study the *broader frames and contexts* in which these developments have taken place. For this reason, I also will look at some historical conditions and incidents, such as the two Asilomar conferences in the 1970s and the ELSI/A programs that emerged in the 2000s with the Human Genome Project (HGP); as well as some other transformative features of medical research and its practice and regulatory responses to it, to provide a broader picture of why bioethics can be seen and thoroughly analyzed as such a kind of governance practice. I will then reflect on bioethics in relation to *public policy* and so-called *"empirical bioethics"* and ask what this "empirical turn" in bioethics means by contrasting it with two common methods favoured by bioethicists: principlism and consensus. Finally, the chapter concludes with some thoughts on the broader *justificatory narratives* that reveal bioethics as a governance practice because it has produced very specific responses to specific problems. This provides a fertile ground on which the subsequent analysis can be based.

4.1 The notion of governance

The *notion of governance* is a ubiquitous buzzword in both the academy and policy institutions. It describes a change in the understanding of how policy and regulations come into being and how they are exercised differently, which is in contrast to a centralized mode of distributing power between regulatory state agencies. Felt and colleagues have emphasized that an imprecise use of the two terms '*governance*' and '*government*' has long been prevalent, meaning that they have often been conflated in both academic and ordinary discourses (Felt, Fochler, Mager, & Winkler, 2008). Despite this, or precisely because of it, the term 'governance' refers to new constellations and cooperative arrangements for exercising power that go far beyond traditional state structures, rules and processes that classic governance denotes (ibid.: 235). Government indicates a state-centred and thus centralized way of regulating and ordering society, while governance describes a much more de-centralized, network-like, and interorganizational way of controlling or regulating society. Or as Rhodes interestingly spun it:

> Focusing on governance can blur, even dissolve, the distinction between state and civil society. The state becomes a collection of interorganizational networks made up of governmental and societal actors with no

> sovereign actor able to steer or regulate. Governance as self-organizing networks is as distinct a governing structure as markets and hierarchies. A key challenge for government is to enable these networks and to seek out new forms of co-operation. (Rhodes, 1996: 666)

Due to the acceleration of techno-scientific developments, areas of regulations have become increasingly complex, and as a consequence, the state and state institutions in consequence are no longer capable of exercising oversight of this complexity on their own. With this shift in focus (from govern*ment* to govern*ance)* bottom-up approaches to policy-making have emerged, which emphasize the increasing importance of involving diverse "publics" (e.g., citizens and civil society groups or stakeholders, or user groups when it comes to technologies) in the form of participatory engagement activities in policy and research strategies. Such forums and strategies aim to enable democratic decision-making processes in times of ethical pluralism, which means raising the question of how democratic and sustainable decision-making can be effectively put into practice. In this regard, Hilgartner and his colleagues have emphasized that the "(…) methodologically foundational STS sensibilities that treat science and governance as objects of critical scrutiny" (Hilgartner et al., 2017: 840).
Since my study focuses on two particular institutional actors in the field of reproductive medicine and ART, my interest lies specifically in how such professional societies, as a potent part of civil society, participate in this kind of governance practice and aim to order the moral fabric of reproductive medicine.
In addition to extensive document analysis, I also conducted a series of field visits and conversations with stakeholders at relevant scientific events of ESHRE. These provided me with additional moments through which it was possible to see how they think, speak, and perceive and perform their role in 'governing' (in the sense of steering and ordering) the field (including different actors, issues, objects, technologies) of assisted reproductive medicine. For instance, one can see which kinds of actors are present and invited to speak at such events – e.g. there were dedicated patient sessions where not only patient representatives but also patients who were directly affected (i.e. women) spoke. In these patient sessions, a lot of criticism was articulated about a range of topics, such as the behaviour of doctors in terms of providing adequate information. Nevertheless, the profession (and its discursive or "narrative infrastructure") (Deuten & Rip, 2000; Felt, 2017) is actually rather re-confirmed by these accounts from patients because they validate them precisely in and through such spaces that the profession provides and specifies at these conferences. Another aspect would be who is allowed to participate in the production of documents and the ethical opinions (but more on that later). Or another is in what way they talk about issues at such events or in the documents, this is to say how they present and stage themselves.

This perspective towards bioethics as a practice is not new, particularly within science and technology studies (STS). It is a common claim in STS that all 'academic' disciplines or professional developments are undergirded by a social element which has shaped how they have developed:

> However, the extent to which bioethical practices have been consolidated into advisory and regulatory structures (such as 'ethics committees') is distinctive. (…) It is these processes of institutionalization that I suggest constitute the primary forms of bioethics governance. (Montgomery, 2016: 5)

In addition to the particular form of institutionalization (consolidation into advisory and regulatory structures such as committees) of these ethics committees, I am primarily interested in the specific literary forms of bioethics governance: the ethical statements (including guidelines and recommendations) formulated by them. Hence, I aim to study whether, and if so, how such documents might function as self-regulating, or in other words as justificatory devices and therefore as *"tacit modes of governance"* (Felt, 2017) within and for this particular (bio)medical profession. The forms of institutionalization are strongly linked to the specific forms of dissemination, which makes the bioethical opinion papers an interesting object of study to better understand bioethics as a governance practice. Specifically:

> The forms of dissemination of public ethics are different to those of the academy and these differences are worthy of examination. Studying bioethics as a governance practice focusses more on *who* does things, *how* and *why* they do them, than in *what* they study and what they conclude. (Montgomery, 2016: 20)

Montgomery has emphasized that this particular perspective on bioethics as a governance practice should not replace other approaches but rather ideally complement them if we are to fully understand bioethics in its various forms and modalities. And I would add that the ethics committees of this study are very specific ones, because they are located at an intersection somewhere between academia and public institutions – we could just consider them as part of two boundary or hybrid organizations (Guston, 2001), which are characterized by operating between the areas of policy and science.

Focusing on governance through an STS lens means gaining a better understanding of the developmental tendencies and dynamics of science-technology-society relations and how regulatory processes are carried out under conditions of increasing decentralisation and scientific uncertainty (Beck, Niewöhner, & Sörensen, 2014). I am very much interested in the question of what bioethics means in the context of such scientific institutions as well as what it means in terms of a tacit mode of governance (in the sense of steering and ordering). This has a lot to do with the discursive role of bioethics and the *ethicists* themselves as they exist within such scientific societies, but also the biomedical community in general. That means, whether ethicists function more as "insiders" or "outsiders", as trustful advisers, or rather as critics and corrective, or even as managers; however, maybe one could even come up with many different categories, in any case, this is more of an empirical question.
My aim is to investigate and understand precisely these (re)articulations of ethical (ordering) and regulatory (controlling & steering) aspects and responses through bioethics in the context of these particular institutions (scientific societies), and more specifically, how this is done within these specific professional institutions. Of particular interest is the question of the epistemological consequences of these particular institutional and discursive frameworks of

knowledge production and the increasing integration of 'ethics' [19] into different more and more scientific, but also policy domains.

4.2 The notion of biomedicine: (Bio)medicalization as the broader societal transformation in which (bio)ethics becomes a governance practice

Let us now proceed by taking a closer look at the notion of *biomedicine* itself, to which bioethics obviously refers when it considers ethical issues – often called dilemmas, or characterized by the adjective: controversial – that are raised by its practices. How is it that we speak of the neologism biomedicine, instead of medicine? What conditions have led to medicine becoming biomedicine, especially in scientific problematizations? A quick answer to this question would be that this hybrid notion, which contains the two meanings *bio,* whereby 'bio' refers to 'life' in a comprehensive sense (Foucault, 1987, 2006), and *medicine,* describes the determination of medicine through biology (Bruchhausen, 2010). A more sophisticated answer is provided by Bruno Strasser, who has stated that "biomedicine rests on a specific way of producing knowledge about health and disease: biomedical research", i.e., a particular way of knowing, in which its answers and questions are dependent upon "a set of assumptions about the relationship between science and medicine, health and disease, knowledge and action" (Strasser, 2014: 9). Despite the fact that the concept of biomedicine has different origins and trajectories in English, German and French, from the very onset there is a crucial and common aspect of understanding it as a certain kind of medicine, namely one that is "(...) closely associated with experimentation and the laboratory rather than doctor's knowledge and the clinic" (ibid.). This defining feature of biomedicine, one that is intimately interlinked with both the laboratory and clinical research, has had an enormous influence on the institutional, political, as well as intellectual development of medicine. As Strasser aptly puts it:

> The transformation of medicine into biomedicine was understood as being one of the modernizing projects of Western nations, in which scientific rationality served as a guiding principle. During the mid-twentieth century, this notion of biomedicine as modern medicine came to be associated with two sets of related meanings. First, biomedicine became "molecular medicine", i.e. laboratory research about the role of molecules in health and diseases. Second, biomedicine became synonymous with "Western medicine" (the kind of medicine institutionalized and dominant in Western countries) as contrasted with "non-Western" medicine (the kind of medicine institutionalized in Asian countries for example), "alternative" medicine (the kind of medicine practiced in Western countries but that does not follow the principles of Western science), or "indigenous" medicine (the kind of medicine practiced by healers in communities with belief systems thought to be at variance with Western science). (Strasser, 2014: 12)

The second meaning particularly emerged within social-anthropological problematizations of biomedicine, whereas in sociology or STS, we instead refer to the first meaning. However, both meanings are strongly interrelated and cannot be separated, as Strasser succinctly pointed out.

[19] I put ethics here under quotation marks because otherwise it would seem too clear what ethics and ethical consideration entails. But obviously this is part of my research interest, to pursue also the question which kind of ethics (in terms of its functions and roles within such an institution, in form of its particular expression) becomes performed in practiced and its relation to policy-making (or even politics) and how this goes together with (the performance of) different values, professional as well as public values and interests.

But what indicates this process of rationalization is the strong entanglement of modern medicine with both the laboratory and clinical research (rational Western science).[20] For example, in its definition of biomedical research, the OECD (Organisation for Economic Co-operation and Development)[21] states that biomedical research encompasses a wide range of activities, but is particularly defined by its use of laboratory-derived knowledge of biological processes (often at the molecular cell level) to advance human health. However, along with this definition comes the difficulty of how to deal with the translational process of this relationship, i.e., how to apply laboratory-derived knowledge of the biological nature of disease in the clinic. As Strasser has further stressed, "under this definition of biomedicine, all experimental research on basic biological mechanisms possesses potential relevance to medicine" (ibid.).

What becomes apparent is that the distinction between these two domains – basic research (lab) and applied practice (clinic) – becomes tremendously blurry within biomedicine. While it is clear that the production of knowledge about therapeutics must always include a clinical phase that involves patients, in the biomedical paradigm both phases often occur simultaneously and act on the same subjects (ibid.). However, Löwy, for example, has also shown the extent to which clinical trials in hospitals function like experiments in laboratories and function as practices that simultaneously produce knowledge about the mechanisms of disease and its potential treatments (Löwy, 1996; Strasser, 2014). But it is precisely this definition of biomedical research, in which any research on a basic biological mechanism has potential relevance to medicine, that forms its legitimacy. In such an environment a different kind of ethics is required, a kind in which *medical ethics evolves into bioethics*.

Strasser further emphasizes that during the course of the 20th century, the concept of disease was supplemented with the concept of 'risk'. As a result, this notion of risk has become integrated as a key concept into the biomedical discourse, which transforms "(…) distinct moments of illness into lifelong risks experienced by healthy individuals" (ibid.: 15). Examples of such risks are cardiovascular disease or the 'risk' of cancer, which are associated with tests for biomedical markers rather than recognizable symptoms. In this way, people today also experience their health as constantly threatened, namely accompanied by a constant risk of possible disease:

[20] Already 100 years ago, Max Weber identified the rational experiment and modern laboratory of the natural sciences as a key element of the unfolding modern rationalization (in the spirit of capitalism) in the Western World: „Nur im Okzident gibt es »*Wissenschaft*« in dem Entwicklungsstadium, welches wir heute als »gültig« anerkennen (…) Aber: der babylonischen und jeder anderen Astronomie fehlte – was ja die Entwicklung namentlich der babylonischen Sternkunde nur um so erstaunlicher macht – die mathematische Fundamentierung, die erst die Hellenen ihr gaben. Der indischen Geometrie fehlte der rationale »Beweis«: wiederum ein Produkt hellenischen Geistes, der auch die Mechanik und Physik zuerst geschaffen hat. Den nach der Seite der Beobachtung überaus entwickelten indischen Naturwissenschaften fehlte das **rationale Experiment:** nach antiken Ansätzen wesentlich ein Produkt der Renaissance, und das **moderne Laboratorium**, daher der namentlich in Indien empirisch-technisch hochentwickelten Medizin die biologische und insbesondere biochemische Grundlage. Eine rationale Chemie fehlt allen Kulturgebieten außer dem Okzident" (Weber, 2010/1920a, 2010/1920b). He continued with an enumeration of particular rational forms that have developed exclusively in the Western world, such as phenomena in art, architecture, such as central perspective, but also other particular phenomena: in particular, bureaucracy, which has developed in this specific way only in the Western world, according to Weber.

[21] See for instance here: https://www.oecd.org/sti/emerging-tech/46925602.pdf (accessed on 22nd of February 2023).

> Biomedicine has blurred the boundaries between the restoration of health and the enhancement of the individual. The more general point, however, is that by shifting its aim from the elimination of disease to the management of risks, biomedicine has opened the door to a never-ending pursuit of risk reduction. (…) Historical studies suggest that the boundary between normal and abnormal is the product of complex negotiations between the pharmaceutical industry, physicians, and public health authorities. In fact, 'normal' blood pressure ranges have become successively narrower over time, placing more and more people in the category of patients (and customers) "at risk" and thus in need of treatment. (Greene, 2007; Strasser, 2014: 15)

This process of '*medicalization'* of society indicates a development by which medicine has claimed and expanded its jurisdiction over physical, mental, behavioural and other conditions by creating new categories of disease, such as 'hyperactive syndrome' or 'premenstrual syndrome': „Comparatively few examples of "de-medicalization" exist. The prominent exception which proves the rule was the removal of homosexuality from the Diagnostic and Statistical Manual of Mental Disorders (DSM) II in 1973" (ibid.: 16). This process has essentially helped to maintain and expand the authority of medicine, which is important for understanding contemporary forms of biomedicine as medical practice. This extensive medicalization process has revealed and even reinforced the immense power of the medical profession; however, it is also a fluid category, so who counts as a member at a given time and place is contested (as we can see clearly in debates about the bioethics profession).
More recently, some scholars have expanded this concept with the term "biomedicalization", which refers to another important change in medicine and society (Clarke, Shim, Mamo, Fosket, & Fishman, 2003). Clarke and their colleagues refer explicitly to a transformation in the US-medical context, but despite its specificities and political culture, these processes can also be found in one way or another in other Western countries as well (and perhaps elsewhere, too). They describe a particular type of change that is characterised by technological and scientific intervention, which is characterized by a molecular gaze rather than a clinical one (Strasser, 2014). Furthermore, they emphasize the increasing importance and power of genes (genes that cause disease), which have simultaneously created new identities that, for instance, Rabinow describes as "biosocialities" at both the individual and collective levels (Rabinow, 1996). Thus, with the notion of biomedicalization Clarke and their colleagues want to emphasize an intensification of medicalization through *technoscientific innovations* (biotechnologies, new medical technologies, genomization, transplantation medicine) in new and diverse technoscientific intertwined ways, which, however, also need to be investigated.

By *technoscientific,* we in STS address the particular shape of knowledge production that Strasser, Clarke and other scholars have in mind when they talk about biomedicalization: Biomedical knowledge is not only produced to know about health and disease and its mechanisms and processes at a molecular level but this knowledge is produced in the spirit of *intervening*, which means that it can be used as a technology.[22] Specifically:

[22] This accurate account on technoscience is given by Brian Wynne in the following Podcast: https://www.cbc.ca/radio/ideas/how-to-think-about-science-part-10-1.464987 (accessed on 12th November 2019).

> Institutionally, biomedicine is being reorganized not only from the top down or the bottom up but *from the inside out.* This is occurring largely through the remaking of the technical, informational infrastructures of the life sciences and biomedicine via the incorporation of computer and information technologies (Bowker and Star 1999; Cartwright 2000; Lewis 2000; national Research Council 2000). (Clarke et al., 2003: 162)

This means the extension of medical jurisdiction over health is no longer limited exclusively to illness, disease and injury, but instead goes along with an increasing commodification of health (integrated and packaged especially into lifestyle issues) and is essential to this process of biomedicalization. For instance, the *birth control pill* was an early advent of this shift toward biomedicalization: "(…) the first serious pharmaceutical designed to be taken by healthy asymptomatic people (women). Grave doubts that people would take powerful drugs in the absence of illness were quickly erased by its immediate success" (ibid.: 178). This example also shows that (assisted) human reproduction is indeed a medical field (and a fertile playground) that is closely linked with these invasive biomedical changes, for example, also in the case of technologies such as egg maturation and other reproductive technologies.

What is important in the context of my project is where the authors locate this broader transformation: while they note that it manifests itself at both: a macrostructural level, as well as a micro level (including the formation of new identities and subjectivities), it becomes particularly evident at what they refer to as a mesolevel,[23] which they describe as new social forms and organizational infrastructures. Examples of mesolevel infrastructures include new kinds of organizations and associations, such as e.g. patient organizations, that have become instrumental in structuring (ordering) the biomedical field and thus governing life.

This is also where I would situate my case study because these scientific societies are two particularly relevant actors in the field of reproductive medicine, where one can examine exactly those ordering practices (including potential changes). By focusing on this specific work (written outputs) of the ethics committees, I am convinced that one can also examine the relationship between the knowledge systems of politics and ethics. In my case, rather asymmetrically, I also examine how the practice of bioethics acts and expresses itself in the direction of politics or policy-making, or what potential reordered relationship results from this expression, where ethical positions cannot be seen as end points, but rather should be thought of as the impetus for political action.

In the biomedical age, health is increasingly becoming an individual matter for which everyone must take care of themselves and for which everyone bears moral responsibility. Health, as a matter of permanent moral self-optimization, represents a powerful playground in which people can build their identity more than ever before. It is for this reason that we can speak about health as a profound 'truth regime' of our times constituted through power and knowledge, which are intimately linked within discourses.

Foucault coined the two concepts of ***biopower*** and ***biopolitics,*** which he used to compare the exercise of power in pre-modern and modern periods (Foucault, 1987, 2006). In the first case, he described it as the sovereign's power over death, deciding who should die and who should

[23] I do not necessarily operate with these notions, but just refer to the authors' vocabulary to make the point.

be allowed to survive, while in the second case, a new kind of power emerged that was about the shaping of life itself.

By analyzing discursive developments about the changing truth regimes of earlier centuries, commencing in the 17th century, Foucault identified two main types of *biopower*: the first directed at the body as a machine (individual), concerned with the proper dressing and (self-)surveillance of the individual human body in order to enhance its capabilities (including disciplining in institutions such as barracks, schools, etc.); the second type emerged in the 18th century, which addresses the human being as species (the societal collective as population; or in German: *Gattungswesen*). Consequently, biopower addresses not only the individual but, more importantly, the human population as a whole, and with issues such as human reproduction, birth rates, mortality, public health, and the maintenance and improvement of life expectancy placed on the agenda and increasingly becoming biopolitical arenas. The entire set of issues raised by this comprehensive transformation of biopower points to the multiple changes of information, production and distribution of knowledges within a biomedicalized society (Clarke et al., 2003).

Both scientific societies (ESHRE & ASRM) have their own densely-networked infrastructures, including sophisticated websites, where they provide copious amounts of different information, newsletters, reports (quite different in their kinds, addressing different audiences), and links to other organizations (such as patient organisations) with which they cooperate. Thus, they perform a serious interest in knowledge production and -dissemination (information), while aiming to reach different publics, involving different professionals – such as scientists, practitioners (doctors, paramedical staff), and potential patients (i.e. the concerned public whose members could be one day confronted with reproductive troubles),[24] but importantly, also aiming to reach policy makers.

This is the very characteristic of a biomedicalized society in which a particular form of biopolitics prevails, in which every human being is constantly exposed to risk and carries the potential to become a patient (or at least a person concerned), a circumstance that is translated and integrated into daily actions and life decisions of everyone. And it is within this broader environmental transformation of biopolitics that bioethics gets to play an important justificatory role that needs to be scrutinized.

4.3 Transformation of the medical profession and jurisdictional troubles and extensions

"Medicine is probably the most successful profession, taking away the jurisdictions of others right and left in a process sociologists call "medicalization"" (Evans, 2012: 167). Against this background, there is another important aspect to be mentioned in relation to research and science governance: It is neither solely the role of scandals, new medical technologies, nor the desire of one or the other profession to establish a practice-relevant field or discourse such as bioethics, but it has also to do with the transformation of the medical profession itself, since it

[24] See e.g. ESHRE's involvement to raise awareness for so-called fertility education, http://www.globalwomenconnected.com/wp-content/uploads/2019/10/Screen-Shot-2019-11-01-at-15.21.07.png (accessed on 6th November 2019).

no longer forms a unified profession in a strict sense (as described earlier). Research in healthcare involves a *heterogenous group*, not just doctors, but it also now includes "(…) clinical triallists, epidemiologists, clinicians of various specialities, health service researchers, nurses, social scientists, ethnographers and so on" (Dixon-Woods & Ashcroft, 2008: 385). These professionals are located in different institutions and thus, they are no longer bound to a single ethical code or unitary professional structure:

> There is no single professional association or register, and thus the occupational category of "researcher" is extremely leaky. Research in healthcare thus lacks a single set of explicit standards of professionalism, code of conduct, or set of sanctions imposed from within. (ibid.: 385)

Furthermore, asking questions about "Ethical, Legal, and Social Implications/Aspects" (ELSI/A projects) in a systematic way in the biomedical sciences has been an outcome of the Human Genome Project (HGP) in the 1990s, and for the first time in history incorporated investigation of its own ethical and social dimensions (Hilgartner et al., 2017). This discourse has slightly shifted and can now be seen as situated under the umbrella term of "Responsible Research and Innovation". RRI, can be represented as an attempt to overcome Polanyi's argument on the unpredictability of scientific progress, and instead try to reflect potential outcomes at an early stage of technoscientific development through different means (Stilgoe & Guston, 2017). In this sense, anticipation becomes a requirement in the research process and mutates into a conviction of its effectiveness, which has consequences for research and its knowledge production. However, it is doubtful that this will work, but as an idea and visionary drive, so to speak, it may well have effects that are worth considering if and how, such ideas might be articulated in such ethics committees.

However in the past, such broader societal concerns have led to moratoriums, such as the one decided at the international Asilomar conference in 1975 on recombinant DNA molecules, where internal scientific debates about so-called biohazards led to the moratorium decided at this conference. This singular event, "(…) marked the beginning of an exceptional era for science and for the public discussion of science policy", according to Paul Berg, one of the conference organizers at that time (Berg, 2008).[25] Interestingly, as Berg underlines, the people who sounded the alarm about this new line of experimentation were not journalists and the media, nor politicians, and not even religious groups, but they were scientists themselves (ibid.). The significance of this event was the precedent it set about how to properly respond to changes in scientific knowledge (and its uncertainties), namely by formulating and developing guidelines that should govern how to regulate new scientific knowledge, and which should undergo timely changes in response to the evolution of scientific knowledge instead of strict regulations (Berg & Singer, 1995). Therefore, the relationship between public- and science policy in the domain of biomedicine is relevant because science policy is never merely about how to regulate scientific endeavour but is always at the same time public policy because it is about how to rule life. Though, Evans has stressed that this is consistent:

[25] See: http://www.nature.com/nature/journal/v455/n7211/full/455290a.html (accessed on 13th November 2019).

> (…) with the scientists' acknowledgment of the many challenges to their jurisdiction in this era, many scientists feared that if the public were to become aware of this internal debate about what became known as biohazards, the scientists' jurisdictional defense of HGE [Human Genetic Engineering] and even the home jurisdiction would be threatened by the public trying to control or limit scientific activity. (Evans, 2002: 95)

This means that scientists themselves feared a kind of 'public over-reaction' that could possibly have led to a renewal of fears about genetic engineering and molecular genetics in general. This is one reason why they heavily tried to keep the debate on a technical level, which meant limiting the contested issue to the possibility of hazards and through that justifying that decision-making stays entirely in the hands of scientists. Thus, they struggled to keep it within their home jurisdiction, as Evans has called it, and therefore debated only specific consequences of these experiments, leaving out, for example, "(…) contested jurisdictional arenas, such as whether DNA should be moved between species at all" (ibid.: 96).

At present, we can find similarities to the situation in the 1970s (and Asilomar), specifically through the strong efforts on the part of the professionals concerning the best way to regulate conflicts through and within the medical field itself (specifically in case of assisted human reproduction). We can easily recognize this approach of self-regulation from the organization of such professional societies in general, and in particular through the ethical framings that are performed by the work of these ethics committees to encounter emerging controversial issues associated with the practices of ART. The emerging ethical framing of science or of its resulting ethical issues can be traced back to the increasing criticism of the scientists' exclusively technical approach to solving these problems associated with recombinant DNA:

> More generally, scientists had succeeded in keeping the public, or anyone else, from being involved with decision making. This conclusion was reached by Senator Kennedy, who complained at a hearing after the Asilomar conference that the meeting was "inadequate because 'scientists alone decided to impose the moratorium and scientists alone decided to lift it'. The factors under consideration, however, extended far beyond their technical competence, said Kennedy. 'In fact they were making public policy. And they were making it in private'. (Dickson, 1984; Evans, 2002: 97)

For example, Paul Berg, one of the conference organizers, noted that the threat of legislative intervention in this area of research was pervasive:

> If our recommendations look self-serving, we will run the risk of having standards imposed. We must start high and work down. We can't say that 150 scientists spent four days at Asilomar and all of them agreed that there was a hazard – and they still couldn't come up with a single suggestion. That's telling the government to do it for us. (Evans, 2002: 96; Wright, 1994)

Hurlbut's research on Asilomar and its scientific legacy is also worth noting in this context because he emphasized that this particular event is often remembered as a historic moment in the development of biotechnology, as well as an event that laid the foundation for scientific self-regulation in this specific and potentially dangerous research domain (Hurlbut, 2015c: 126). It marked the beginning of incorporating the investigation of the ethical and social dimensions of biotechnologies by scientists themselves. One of the intriguing outcomes (or

effects) of this event has been the increased public interest in biomedical research and molecular genetics, however:

> On the positive side, widespread reporting stimulates knowledgeable public discussion of some of the social, political, and environmental issues that are, and will be, emerging from genetic medicine and the use of genetically modified plants in agriculture. On the downside is the tendency of reporters, sometimes with the aid of scientists, to overstate the findings or the immediacy of applications to human problems. This inclination is exacerbated by the very competitive situation with respect to grants, and by interests in commercialization. (Berg & Singer, 1995: 1134)

Consequently, Hurlbut speaks about a sociotechnical imaginary that he calls "*governable emergence"* (Hurlbut, 2015b) in the context of Asilomar being such a historical identifying moment for science. As such, this imaginary recognizes 'technoscience' as a source of novelty and thus as a driving force for historical and sociotechnical change. Such an imaginary also attributes agency to the scientific community (or rather, profession), which acts (in terms of having agency and responsibility to do so), while society, in contrast, merely reacts (ibid.: 128). It further implies that sociotechnical change and its emergence is and should be governable. As a result, the profession tries to achieve a gatekeeping role in governing technological emergence, not based on a principle of scientific autonomy but rather grounded in the imaginary that science is the institution most capable of doing so. Moreover, he also shows how such an imaginary develops and privileges science and defines law – and more so, society as a whole – as backward. Similar to Evans, he therefore concludes:

> We are invited to worry only over the end products of science, not about its processes of judging what forms of research are desirable and good. In short, Asilomar underwrites the notion that those who are in a position to make the technological future are also the most competent to declare what possible futures warrant public attention. This renders society and its institutions inevitably and perpetually reactive. (Hurlbut, 2015a: 12)

This also touches very critically on the problem of balancing scientific knowledge or findings (so-called facts) against questions of values and interests, with the latter being successively excluded from discussions on technoscientific developments. For my project, the Asilomar event (as a historically unique event) is worth considering (or at least bearing in mind) in the sense of whether and to what extent the effect of this incident is also present in the two cases discussed here – that is, primarily the imaginary of a so-called *'governable emergence'*. I will trace this by examining the work of their ethics committees, especially by analyzing their argumentative practices in their ethics reports. I will do this because I think that the argumentations and modes of justification in these cases are of utmost importance in order to understand bioethics as a governance practice. Thus, sociological or STS-analyses of this kind, as developed by Evans, or Hurlbut on professional developments and the embeddedness of bioethics in the overall biomedical apparatus are particularly helpful points of references in pursuing exactly this question of (self-)governance.

From the sociological perspective of professional development (and connecting to the earlier section), Evans has also shown how *principlism* (as an abstract knowledge system) and the

consensus method regularly used by bioethics committees, have formed one of the cornerstones of the foundation of this profession, in which the methods and reasonings are co-produced with the very institutions in which bioethics becomes operative and consolidated. This also shows how such a decision-making system shapes – also in the sense of constraining – the way issues are made governable by this particular bioethical work. For this reason, in the next section I address some further contextual elements in which the emergence of bioethics – as a particular discursive field – should be seen.

4.4 Bioethics and its principles in the context of justificatory processes

Bioethics has grown out of moral philosophy as well as radical, transformative developments in medical health care systems and structures that, as explained earlier, have occurred primarily in Western health care systems. It is part of a model of so-called applied ethics, which in its most well-known form involves the application of a limited set of principles to achieve ethical justification for research as well as for medical practice and its technologies. It thus represents the framing, and in this sense a kind of preparatory support or rather impetus for actual medical decision making. As such, it represents a particular way of structuring the biomedical field that must work through the relationship between moral theory and moral practice and therefore wrestles accordingly with the long-standing distinction between fact and value, object and subject. This particularly problematic form has been further reinforced by their particular individualistic decision-making system that of principlism. Specifically, all of those principles e.g. 'beneficence' (doing good, avoiding harm) work quite well in the two-task system of bioethics (research bioethics and health-care ethics consultation) according to Evans, but do not necessarily work in the domain of public policy bioethics (Evans, 2012). The issue here is more about what he calls the 'cultural harms' of using certain technologies:

> Cultural harms cannot be effectively described using an individualistic ethical system like principlism, so if these concerns cannot be transmuted into principlism, they are discarded, effectively discarding much of the criticism of a technology. This results in an inability to say "no" to an emergent technology using principlism. (Evans, 2012: 115)

I will return to this aspect raised by Evan's analysis of principle-based bioethics and what this means in practice for bioethical reasoning in a later section. But now I will discuss the other central method of bioethics: consensus, which functions in much the same way, in the sense that it precludes specific responses from the outset, such as saying 'no' to a new, emerging technology. Consequently, bioethical considerations are hardly about the 'desirability' of a new technology or innovation, but rather about the 'how', i.e. what the implementation and (concrete) applications might look like and, above all, on what basis of justification these decisions can be made.

Hedgecoe, for example, juxtaposes "critical bioethics" with this classical principle-based bioethics (principlism), as well as other bioethical approaches. Critical bioethics is strongly inspired by social sciences and epidemiologists, while principlism, as noted earlier, adheres too much to theoretical and universalistic claims and does not ground its claims in social reality, according to Hedgecoe. Despite his critique of principlism – the lack of empirical grounding of

its claims – he still points to Beauchamp and Childress, the main founders of this normative bioethics approach, who described the relationship between theory and practice as follows: "(…) cases provide data for theory and are theory's *testing* ground as well. Case leads us to modify and refine embryonic theoretical claims, especially by pointing to inadequacies in or limitations of theories" (Beauchamp & Childress in Hedgecoe, 2004: 138; *emphasis added*). At the same time, this quote shows the discrepancy or break between theoretical thinking and practical implementation, which, it is worth noting, is also a challenge for every idea and theory in this world without exception; conversely, no idea arises out of nowhere but is always anchored in social reality in some way. Hedgecoe underlines the relevance of applying such a *testing element* in practice.

One cannot deny the similarity to Boltanski's and Thèvenot's analysis of justificatory processes and the "orders of worth" approach, which aims at reaching an agreement – a consensus – between people. In their studies, they have been concerned with the configuration of public space, the sense of the just and the dynamic of public discourse, which led them to develop a theoretical framework that is concerned with one important social element of interaction, namely how people justify what they do, and in which the testing element also plays a central role (Boltanski & Thévenot, 2000; Sharon, 2018). This constitutes an interesting framework for examining bioethical decision-making and actually its particular indecisiveness:

> Indeed, for persons to be able to reach an agreement in practice, not only in principle, a **reality test** has to take place, accompanied by a codification or, at least, an explicit formulation of valid proof. (…) To be able to converge towards an agreement, persons really have to refer to something which is not of persons and which transcends them. This common reference we call a **principle of equivalence**. To criticize or to justify, the persons have to extract themselves from the immediate situation and rise to a level of generality. Therefore, they turn to seeking a position by relying on a principle that is valid in all generality. (Boltanski & Thévenot, 2000: 213; emphasis added)

This is exactly what the four-principle model proposed by Beauchamp and Childress does. Through the rather abstract principles of autonomy, justice, beneficence and non-maleficence, it reaches a level that is beyond the immediate situation and case, but which should in reverse be applicable to every case in practice. Further, it removes the problems at stake to a higher level of abstraction (that of general principles) and makes it possible for followers of even radically different theoretical (or normative) standpoints (utilitarianism, consequentialism, deontologists …) to agree upon them. This is the reason why it can function as justification on a general level regardless of different personal or normative viewpoints. These principles are generalizable and can be recognized by others in this discourse:

> The authors refer to these as moral repertoires or orders of worth: coherent vocabularies of argumentation and justification that are each organized around one vision of the common good. They suggest that six such repertoires, each based on different philosophical foundations concerning moral worth, are commonly appealed to Western liberal societies (…) Each repertoire acts as a logical, harmonious order of statements, objects and people, that provides a general sense of justice. (Sharon, 2018: 4)

Boltanski and Thévenot have identified six of such repertoires, or moral orders of worth, when it comes to justification: the 'market' worth (economy), the 'civic' that embraces the logic of

equality and solidarity (collective), the 'industrial (based on efficiency and technical competence), the 'domestic' worth (based on trust, personal and local clues), the 'inspiration' (expressed in creativity), and emotion or religious grace and the 'renown' (entrenched in public opinion and fame). Thévenot and colleagues identified a further emergent order of worth, the 'green' that reflects principles of environmentalism (argumentations that invoke renewable, sustainable and recyclable handling with natural resources) (Lamont & Thévenot, 2000: 237). Tamar Sharon has identified another, 'vitalist' one, which views health as a higher common principle with intrinsic value (the common good as greater health, proliferating life) (Sharon, 2018). The last one in particular is of special importance in this context. However, I do not operate with the typology of the 'orders of worth' in a strict sense because I think the concept does not provide enough insight in the case of bioethical argumentation (how I view it here). Instead, I focus on their *justificatory work* as crucial part and activity, especially when examining its literary productions as outputs of their bioethical decision-making work.

Yet, one main difference between this theory and other theories of justice is that Boltanski and Thévenot stress and try to investigate the *"situated sense of the just"* (Boltanski & Thévenot, 2000: 216), by which they mean situations where participants have to explain their judgement by drawing from the resources of the present situations. This may seem to be, at first glance, in contradiction with the above operation of justification, but what they suggest is that the social scientist has – if the aim is to examine the underlying view of justice in all generality – to *"follow the arguments and criticism of the actors,* instead of doubling them with our own operations of calling into question" (ibid.: 218). Regarding this situated sense of the just, the authors further specify:

> We would like to show that tackling **justice in practice** is not simply the empirical side of a theory of principle-driven justice. Entering the issue by the situated judgement leads to the modification of the theoretical models and to the taking into consideration of, notably, the question of how conventional clues are developed and how common objects are qualified. **Justification relies on these operations**. (ibid.: 216; emphasis added)

Bioethical considerations in such ethical opinion statements are an interesting site to examine such justificatory arguments. How the balance is struck between universal/general principles and the empirical, situated evidence of their claims in relation to particular reproductive situations and socio-technical constellations in the case of the ESHRE's and ASRM's ethics committees is also an intriguing question and will be taken up again in the analytical section.

Of course, it is important to point out that I am not examining how such ethical positions of scientific societies are confronted in medical practices (i.e., whether they play a role, and if so, in what ways they enter into concrete medical practice). Instead, I look for how medical practice, including various medical situations and reproductive technologies, itself is imagined in this particular ethical discourse and decision-making process, that is, what and how the empirical side (medical and research practice: practitioners, clinics, laboratory and reproductive technologies) itself becomes the topos of a bioethical negotiation in these papers, as it were, the object of their justificatory reasoning.

In a final step in this conceptual section, therefore, I will consider relevant literature on the relationship between bioethics and public policy-making, as well as what might be called 'empirical bioethics'.

4.5 Bioethics and public policy-making

"If the political is to roll the dice, the ethical is to shake the dice perpetually without rolling. (…) But once the dice land, a particular number is actualized from out the virtuality of the number space" (Galloway, 2014: 187). With this quote in mind, one cannot help but reflect on the misguided actualizations of the ethical project and let this, in turn, become the object of a particular policy, which is why these two dimensions – *the ethical and the political* – must be seen as two sides of the same coin, and thus they are in an inseparable relationship (Doll, 2016). In this last subchapter, therefore, I will continue with some reflections on the relationship between (bio)ethics and politics. In doing so, I will return to some of Evans' reflections on the jurisdictional areas of bioethics, its justifications, and the relationship of its tasks to those of physicians and scientists. Similar to Montgomery,[26] I think the concept of jurisdiction is useful in providing a framework for reflecting on governance questions (Montgomery, 2016), especially when considering the development of professions. But I also think it is necessary to complement these strands of thought with other considerations, such as those related to the work of justification that is necessary to support and justify bioethical decisions in the context of ART. This entails a slight shift in emphasis, namely from the focus on professional developments to the argumentative and justificatory work that assembles the profession with its spaces and issues that constitute each other in the first place.
In a further step, it is also valuable to consider the areas of so-called 'empirical bioethics', because the notion of evidence takes on a special meaning in ethical considerations, through which certain arguments (including, for example, human rights) are highlighted, substantiated or even developed. Consequently, the relationship between human rights and bioethics will also be touched upon (especially in Chapter 7). This is because both areas of ethical problematization provide concepts, practices, and institutions of governance that have a profound interest in influencing the practice of medicine, health policy, and the life sciences with their biotechnologies more generally (Ashcroft, 2010: 639).[27] In addition, I will also discuss some key literature that explicitly addresses bioethics as a governance practice, i.e. a particular type of politics.

4.5.1 Jurisdictional task spaces of bioethics

I will continue here with the theme from earlier in this chapter, specifically with Rosenberg's assertion that bioethics has taken up residence in the belly of the medical whale, or in Evans'

[26] Between 2012 and 2017, Montgomery was a member and chair of the Nuffield Council of Bioethics in the UK.
[27] Some scholars are even claiming that bioethics will one day be subsumed into the international human rights system (Faunce, 2005).

words "(…) the watchdog does not create the rules but is enforcing the rules of the master (…)" (Evans, 2012: 102), i.e. a profession with a watchdog function cannot create its own methods or system of abstract knowledge. In what follows, therefore, primarily with the help of Evans, I will try to think through what this supposedly special position that bioethics has taken within the biomedical apparatus means for its work.

In his work on the history and future of bioethics, Evans (2012) distinguished between three task spaces of bioethics: research bioethics, health-care ethics consultation and public policy bioethics. It is in the last space that Evans located the origins of some jurisdictional crisis of bioethics. As noted earlier, health-care ethics and research bioethics are the jurisdictional areas that have emerged in certain ways and that Evans attempts to capture with a specific notion from the sociology of professions: *"*settlements in the jurisdictional space*"* (ibid.: 103). With this notion, he describes more or less the same process that Abbott has called "subordination", in which one dominant profession leaves subsidiary actions to another. One classic example of such subordination would be the relationship between doctors and nurses and another would be the relationship between doctors and X-ray technicians. The latter ones, for example, do not have their own system of abstract knowledge but rather use that one of the superior profession, which is in the position of defining the language, spaces and tasks accordingly. Medicine is a classic case of having full jurisdiction over particular work, "where those not in the profession who engage in tasks that the profession has jurisdictions over (like surgery) are put in jail" (ibid.: 103). Evans clarifies the two-original task-spaces of bioethics in the US as follows:

> In research bioethics, the task is to be the watchdog by enforcing the established system of ethics set by the federal government, not to create one's own ethical system. In health-care ethics consultation, mediating ethics disagreements is not a watchdog task, but the task of making sure that these ethical decisions stay "within the bounds of ethical and legal standards" is such a task (American Society for Bioethics and Humanities 2011: 10). (ibid.: 102)

Here, Evans describes bioethicists as acting as a kind of watchdog by applying externally determined ethical codes (or norms set by a government), so to speak, and for this purpose, they must be inside the house, otherwise they cannot see any transgressions in progress. What both Evans and Rosenberg mean with the idea of externally derived ethical norms is the creation of specific tasks and rules by scientists (research bioethics) and physicians (health-care bioethics) before bioethicists even entered these debates.

Hence, with the notion of settlement and/or subordinate jurisdiction, it is easier to understand if that process of being *the watchdog inside the house*, or in Rosenberg's words, how and for what reasons it has occurred that bioethics has residence inside the belly of the medical whale (Evans, 2012; Rosenberg, 1999). When considering the two task-spaces of bioethics, it is striking that they do not really challenge the responsibilities and jurisdiction of the medical profession or researchers, but rather support them. Health-care consultation and research ethics have, for centuries, been part of the physicians' and scientists' own jurisdictions, which, as Evans argues, limits the scope of action and argumentation of bioethicists in a particular way:

> For example, in health-care ethics consultation, bioethicists still considered the task to be one of resolving the individual medical dilemma, involving an individual patient, not larger debates about, for example, whether hospitals should be profit-making. Similarly, in research bioethics, scientists had already defined the task in similarly individualistic terms – "should this one particular experiment (not a class of experiment) go forward?" and the only relevant issue was the effects on research subjects, not the effect on society, or questions about the purpose of science. (Evans, 2012: 105)

More importantly, these two task-spaces have, according to Evans, themselves structured the methods for ethical decision-making that bioethicists have subsequently further developed. For example, in the case of the principle of 'respect for persons' (principle of patient autonomy[28]), it becomes clear that it justifies actually the long-standing informed consent process, "(…) but if one starts with the practice of informed consent, there is only a limited range of principles that can be created" (ibid.: 106).
Similarly, the principle of 'beneficence' can originally be traced back to the Hippocratic Oath, specifically 'do not harm'. One innovation, as already pointed out by Beauchamp and Childress themselves, was the 'newly' established principle of 'justice' in biomedical (research), which was also included in the Belmont Report and seeks to regulate the fair selection of research subjects. According to this rule, researchers may not select subjects randomly or because certain ones are readily available; instead the selection process must be balanced and fair. Consequently, the principles were basically a return to practices that had already long been used by scientists and the medical profession. Thus, for the beginnings of bioethics, the author concludes:

> (…) bioethics forced the scientists and physicians to clarify and rigorously apply the procedures that had supposedly already been put in place by the scientists. (…) The bioethics profession's task is to enforce the internal values of the medical/scientific profession *in these two task-spaces*. (ibid.: 107)

Evans has concluded that the ethics of bioethics are the same as the ethics of science and medicine, and that they, therefore, enforce these ethics rules within the houses of scientific research and medical practice (clinics and research settings). But these are far from the only places where bioethics becomes operative. In the meantime, a number of different forums and institutions where bioethics has become incorporated and active have emerged. This is precisely the reason why it is of particular importance to also examine these different 'houses' (or to remain in Evans' words: spaces) where ethics committees and bioethicists are embedded and generating certain outcomes, and where one can examine the different dynamics and developments of argumentative structures and modes of justification.

With this subordinate jurisdiction, however, some difficulties also arise with respect to critiquing the abstract knowledge system used by the superior profession, which is one reason why professions usually seek full jurisdiction for themselves. Dzur, however, in contrast to many other analyses, has pointed out that it is precisely for this reason that bioethics has developed as a form of *"regulatory ethics"* that allows ethicists to play a powerful internal role within

[28] It is actually assumed that this is realized by choice (namely by yes/no choice, i.e. through the informed consent).

organized medicine (Dzur, 2008; Evans, 2012). Some scholars also formulated this particular condition in more clearly political science terms, calling it "institutional capture" or "regulatory capture" (ibid.), and in doing so, describe bioethics' inability to address issues that are fundamentally against the interests of physicians and/or scientists.[29] But Evans also emphasizes the advantage of this particular jurisdictional settlement between medicine/science and bioethics:

> By being literally inside of the hospitals with health-care ethics consultation and inside the scientific research enterprise with IRBs, bioethics is in a position to actually prevent ethics abuses from happening. You have to be inside the fence to guard the house. The task could not be conducted by a profession that was not allowed to be on the inside. (ibid.: 109)

The core problem of the jurisdictional crisis of bioethics, however, starts in the task-space of public policy bioethics (i.e. the third space which Evans primarily deals with). Bioethics has occupied this area from the very beginning, namely in the form of e.g. national ethics committees, but also other forms of bodies dealing with public policy-making. In this task-space, it is not so much the medical or scientific profession that constitutes the jurisdiction-giver, but rather the government and other state-related institutions.

According to Evans, it is the task-space of public policy bioethics that is perhaps destined to be unstable from the outset because it is unable to say 'no' to a technology due to the argumentative decision-making system of principlism. There are two interrelated problems with the application of principlism in this particular area of bioethics. The first occurs when bioethicists successfully describe the ethics of a new technology (e.g., human germline gene editing or embryonic stem cell research) in the language of principlism, because it can then be addressed through ethical analysis within the purview of research bioethics:

> The ethical problem has been redefined from one to be discussed in the public policy bioethics jurisdiction with unknown and controversial ethical implications, to one with well understood and ordinary ethical dilemmas that should be discussed in research bioethics. If it is in research bioethics, it is an issue that research can begin on, because the task is to evaluate *proposed* research studies where the ethical problems can be handled routinely. A successful transmutation to principlism in public policy bioethics always means "yes", because transmutation makes the issue a research bioethics issue. (ibid.: 114)

That is, because they apply the method of principlism to public policy bioethics as well, they transfer claims into this ethical system, and therefore it obviously does not allow them to say 'no' to a new technology. This, in turn, harms the bioethicists' jurisdictional claim because they are not realizing their role of evaluating and recommending public policy on these issues if their applied evaluation system always results in a 'yes' answer; ""No" in public policy bioethics comes from claims that resist transmutation" (ibid.).

This also fits quite nicely with the empirical analysis of Braun and her colleagues on ethics commissions in France, the UK and Germany, where they concluded that these ethics committees are characterised by what they call *"proper talk"*: "Those who take up a rigorous

[29] Under this term, we can also chalk up "corporate bioethics," which I have already touched upon earlier in this chapter.

normative position lack the decisive competence that a good member of the ethics regime must bring: the disposition to consider all positions as discussable" (Braun, Herrmann, Könninger, & Moore, 2010: 851). This means that a member of an ethics committee must subscribe to the acceptance of the medical technologies or research projects under discussion as well as to the ethical reasoning system (principlism), otherwise – as in case of fundamental rejection – they will not be able to exercise the kind of decision-making expected of them (by the superior biomedical profession, or governmental institutions, so to speak). Thus, it is not so much a specific professional competence that such a member must possess, according to the authors of this study, but rather a particular habitus characterized by an open and flexible attitude that goes hand in hand with the precarious, reversible, and temporary nature of their recommendations and regulations.

The next problem we face here is due to the fact that the principle-based method is an individualistic decision-making system (Evans, 2012) that is primarily applied to research trials and health-care decisions. This makes it rather difficult to consider the social dimensions of a technology. Hedgecoe has similarly addressed this problem, formulating a kind of "social science critique" of bioethics because bioethics always assumes that the individual is the proper measure of all things ethical (Hedgecoe, 2004). Autonomy, for instance, asks whether the patient or (research) subject has given informed consent, and non-maleficence asks whether any of the individuals involved, for example in a clinical trial, are potentially harmed by the new drug being tested: ""Autonomy" on a social level is almost nonsensical. "Justice" is potentially a social concept, but is not really used much by bioethicists outside of research bioethics" (Evans, 2012: 115; Jonsen, 2003). Or, for another example, harm at the individual level (physical harm to a body) also works quite well, but at the social level it is much more subtle and intangible and perhaps non-consensual, so Evans:

> For example, non-bioethicists who compete with bioethicists for jurisdiction in cultural bioethics often raise the issue of cultural harms, such as the idea that certain technologies will harm humanity's conception of itself. Cultural harms cannot be effectively described using an individualistic ethical system like principlism, so if these concerns cannot be transmuted into principlism, they are discarded, effectively discarding much of the criticism of a technology. This results in an inability to say "no" to an emergent technology using principlism. (Evans, 2012: 115)

Evans has also shown how human genetic engineering became a legitimate experimental practice, and thus a part of medical research. This is because bioethicists converted it successfully into the common ethical language of principlism and described it accordingly in terms of beneficence, nonmaleficence, autonomy, and justice. The point is that when social concerns (such as "What should the purpose of human evolution be?") are transformed into individualistic principles, the only way to argue for an intergenerational purpose is to ask whether the autonomous decision-making of people who do not yet exist would be violated if they do not give their consent to the experiments (ibid.: 116). However, if there were a contradiction, better arguments could be made by not using principlism. Evans goes one step further and claims that once this procedure is safe or thought to be safe, it will become part of

the tasks of the medical profession, "(...) because there is no way to make social arguments against it using the current version of individualist principlism" (ibid.).
For this reason, I will now consider two further aspects that characterize bioethical work: first, the prevailing approach of *'consensus'* (precisely the reason why the 'end product' of bioethical decision-making is so interesting: the ethical opinion statements as representing, among other things, such consensus and, more rarely, dissent), and second, *'empirical bioethics'* as an attempt to integrate further (more diverse) arguments into bioethics, both of which also reveal bioethics, in a sense, as a kind of boundary actor.

4.5.2 Boundary work: Consensus approach and empirical bioethics

Another main method of bioethics is *consensus,* which has the same tendency to avoid a 'no-vote' when discussing and evaluating new technologies. In this context, the composition of the bioethics commissioners is not irrelevant because, as Evans noted, a majority of their members are scientists and physicians (i.e. M.D. commissioners), especially in the US, which again can be taken as a sign that the bioethics profession does not have full jurisdiction over the ethics of science and medical practice. The composition of committee members is key because different disciplinary and professional backgrounds involve different versions of ethics. Evans described it as follows:

> In my analysis of commissions, I have found that it is the bench scientist and ordinary M.D. commissioners who have a very constrained version of ethics. (…) The ordinary scientist or physician commissioner believes very strongly in relieving human suffering. Indeed, that is probably why they became scientists and physicians (…), so they want to see technologies that can relieve suffering proceed. They are also very interested in discoveries about nature. Obviously these are noble goals and are shared by the other commission members. However, their ethical concerns tend to stop there whereas the other commissioners bring a wider range of ethical concerns to the table. Of course, some scientists may have additional values and concerns, but they did not derive them from their day jobs, as I would argue that the institution of science in the United States – particularly at the elite level – only teaches the relief of suffering and the value of discovery as important values. (…) This means in practice that ethical concerns about a technology that cannot be transmuted to beneficence and non-maleficence will not achieve consensus as legitimate concerns, and the consensus method means that principlism needs to be used, with all the attendant problems (…). (ibid.: 118)

Evans continues with some of the *justifications* used by bioethicists for their (subsidiary) jurisdictions in the public policy bioethics domain and how they run into trouble with the ones they put forward. The main question that arises here, and which is not considered deeply enough by the bioethics profession is: "How is it that I am in a position to address these particular kinds of questions in the forms and approaches I do, and to the audience and with the authority and sponsor I have" (Belkin, 2004: 378). In this context, three main justificatory arguments can be highlighted: The first is what Evans calls "interest group liberalism", which does not really solve the jurisdictional crisis in public policy bioethics because it can only represent a subset of the population. The second one emphasizes the "technocratic legitimacy" evoked by the methods and approaches used by the bioethics profession, but which is also not a legitimate approach or justification in a liberal democracy. The final one, which is regularly invoked by bioethicists, is that they represent a kind of "common morality", which is the most

powerful one. However, it is also not very credible, because, despite their claim to represent a common morality, the profession actually seems to be using a form of technocratic legitimacy for the basis of its claims (Evans, 2012: 128).

The principlism of the common morality, so to speak, is not so much the problem here, but rather the way in which certain principles are determined. Those principles are supposed to be those upheld by the American public at large (Evans, 2012).[30] Instead, the bioethics profession simply transfers or extrapolates the values of the public in health care ethics consultation and research bioethics to debates about public policy. The public, however, has never really been asked about its values. He further suggests that the bioethics profession's jurisdiction would be much stronger in the area of public policy bioethics if they would explicitly claim that they should occupy it because they represent the public's values. However, this will be not achieved when the profession uses a form of technocratic legitimation for this claim, because:

> (…) it is not possible to create one system of abstract knowledge that simultaneously uses the values of the public and tells the public what their values should be. While such changes may seem painful, if you look at the history of the professions, such changes have always occurred. (…) This is simply part of "professionalization" – creating a more coherent profession. (ibid.: 169)

Similarly, Felt and her colleagues have pointed to the same problem of presuming the public interests in (bio)ethics committees, which are involved in the institutionalization of ethics in form of these expert committees (Felt, Fochler, Müller, & Strassnig, 2009). Evans thus continues his argument by articulating some suggestions for changing the abstract knowledge system in bioethics, with social scientists playing an important role. Specifically, social scientists should empirically identify the diverse values and principles of the public and bioethics would then be more clearly known as the profession that weighs and balances these various principles of the public in relation to a medical or scientific technology (ibid.: 129). However, this also means that bioethics should step back from, what he calls, cultural bioethics because that role – fathoming the values of publics – could or should be taken by the social sciences. This would constitute a profound instance of boundary work by claiming jurisdictional power for the social sciences when it comes to the exploration of public values. The social scientist would assume jurisdiction, so to speak, over the space of cultural bioethics, where it would have the task of empirically determining the values/principles of the public. For this reason, I will now focus on so-called *empirical bioethics*, because this is the area where these issues could potentially be addressed.

Empirical bioethics

In this context, public engagement and participatory approaches have become more and more central, but simultaneously Felt and her colleagues note how difficult it is to engage publics in discussions about increasingly abstract technoscientific trajectories:

[30] It should be noted that Evans has revised his analyses several times, or at least has attempted to examine public policy bioethics from different perspectives and with changing approaches. Nevertheless, I suggest that some of these claims are still important when turning later to the document and justification analysis.

> The significance of empirical social sciences for ethical reasoning has been vividly discussed in bioethics journals under the label of "empirical ethics" over recent years (e.g., Haimes, 2002). Given the competing role of both approaches in the policy realm, this debate may also be read as an example of disciplinary boundary work (Gieryn, 1999) on who is legitimized to give advice on issues concerning science-society relations. (Felt, Fochler, et al., 2009: 356)

In terms of the sociology of the profession, this could be interpreted as a competition over different jurisdictional tasks-spaces. However, the authors further elaborate on similar shortcomings of the principalist bioethics approach, which is ill-prepared to meet the complexity of social issues involved in socio-technical future-making. Like other scholars, they also argue for a jurisdictional task division in which social sciences should empirically identify the interests, values, and principles of the public, while ethicists could play a key role in analyzing these values and principles in different contexts and decision-making situations (ibid.). At the same time, some scholars have pointed to problems that occur in empirical bioethics as well, particularly of a methodological nature by using social science methods (Ashcroft, 2003). Ashcroft provides a very reflexive account of some of the problems associated with the empirical (bio)ethics that he locates, in accordance with a Foucauldian stance, in the context of a particular social and historical formation that he calls *'modernity'*:

> (…) in which moral and ethical categories appear to be empty of content, and whose content can only be supplied by investigation of socially expressed preferences or values, and by democratic (or quasi-democratic) determination of these values and preferences as normatively binding for us, now. (Ashcroft, 2003: 11)

This statement underlines, on the one hand, that the empirical determination of these values can be regarded as typically modern in the sense that a " (…) reflexive representation of society in the production of ethical knowledge becomes a central epistemological claim" (Felt, Fochler, et al., 2009: 357), in which specific paradoxes are present. These representations are also tangled with the production of social order, which is why empirical methods (such as public engagement and participatory approaches) must be viewed not only as representations but also as a performance of social realities and ethical norms. Therefore, both representation and performance must be central methodological questions when it comes to elaborating the values and principles of the public sphere in participatory settings. Specifically, from Hedgecoe:

> Reflexivity is a broad term acknowledging the inter-linked nature of subject and object. At its most simple, it 'presupposes that, while saying something about the "real world", one is simultaneously disclosing something about oneself.' (Pels 2000: 1). In describing and representing the world, we necessarily constitute that world. (Hedgecoe, 2004: 138)

This brings us back to the notion of co-production, because it also attempts in a specific sense to capture the intertwined nature of the subject and the object. Ashcroft problematizes this very issue in the context of the so-called "empirical turn" in bioethics when he states that "(…) the social science contribution to ethical praxis is fatally compromised by the unarticulated role of power relations in constituting the practice of social research and its object" (Ashcroft, 2003: 11). Thus, he raises the following questions in relation to empirical bioethics: e.g., what political

and social order is brought into being through the conduct of public participation, or what order is sought through such processes, and what disorder is imagined or theorized as the basic condition for enabling such processes? He concludes that such empirical bioethics must also be understood as a kind of politics, namely one that, using social technologies, such as group discussions or surveys (which involves certain visions, assumptions, kinds of arguments, decisions, and representations), attempts to maintain a kind of civic stability while simultaneously changing it in the interests of the competing and/or cooperating actors that make up society.

Thus, I propose to explicitly consider participatory approaches to empirical bioethics as policy efforts and forums that participate in shaping public policy in a democratic society (e.g., by informing bioethical debates on various topics and their experiences in the 'public sphere'). At the same time, those participatory formats discuss or bring forth different understandings of politics and science, which in turn can make a valuable contribution to a democratic culture of discussion, sensitizing and promoting among all participants – researchers and scholars alike – with regard to a democratic understanding of politics (or the development thereof). I therefore echo Evans, who in turn refers to Michael Walzer's position in this regard:

> I think that technocracy is illegitimate in a liberal democratic society. I share philosopher Michael Walzer's position that "it is a feature of democratic government that the people have a right to act wrongly (Dzur and Levin 2004: 335). If the citizens want to (stupidly, in some views) ban embryonic stem-cell research, then it is their right to do so. As Dzur and Levin summarize, "if democratic legitimacy means collective decisions by the individuals who are the subjects of those decisions, the role of the philosopher in a democracy cannot be to determine the proper results of those collective decisions" (Dzur and Levin 2004: 335). (Evans, 2012: 125)

Consequently, I think it is extremely important to study bioethics as a governance practice, especially in different socio-political and institutional settings. This is one of the reasons why my study focuses on two so-called scientific (i.e. professional) societies in the field of ART and their role as a kind of boundary institution that tries to steer and thus influence public policy in the context of reproductive science and medicine with different strategies (e.g. collaborations and funding) and diverse tools (e.g. ethical opinion papers, guidelines, recommendations, and others).

4.5.3 Two interrelated justificatory narratives within which bioethics operates

If one wants to understand bioethics and its institutions well, it is crucial to pay attention to the socio-political contexts in which they operate (Montgomery, 2016). Montgomery, for instance, has sketched an agenda for *studying bioethics as a governance practice* and emphasized, among other things, that: "Some institutions may look similar but have different roles and scopes. (…) Bioethics governance should, therefore, be considered in terms of its functions as well as its institutions" (ibid.: 5). A jurisdictional perspective, as it is forwarded by Evans, enables both descriptive as well as normative questions to be identified. However, Montgomery calls attention to considering separately how the jurisdiction came to be constituted and whether it can be defended as legitimate – both of which Evans has analysed together.

As outlined above, one main feature of contemporary bioethics is that it has taken a 'public turn' in which it "(…) constitutes a resource for the formation of public policy which impacts upon the social world" (Priaulx, 2013: 8). Referring to Hävry and Takala, the author states that bioethics is not a fixed entity with a definite meaning, but rather a project which is developing, ever-changing and a multifaceted one:

> Is it only about medicine, nursing and healthcare? No. Is it only about law and regulation? No. Is it only about philosophy and philosophical ethics? No. Is it only about social phenomena and their interpretation? No. Bioethics embraces all these and more. (Häyry & Takala, 2003: 1)

Montgomery further suggests that we should seek to understand *what* bioethics *does* rather than *what it is*. In Foucauldian terms, this would mean viewing bioethics as a discursive technology of social control, and thus seeking a normative framework that could provide a sensitive critique "(…) to the way in which bioethics asserts its jurisdiction in matters of public significance (…)" (Montgomery, 2016: 10; Rose, 2007). This is another reason why it is so important to examine the very arguments that bioethics put forward and the institutions in which it is embedded because it shifts our focus from these practices as intellectual enterprises to an understanding of them as governance practices.

The author summarizes four categories of ethics committees that somewhat map the jurisdictional areas of bioethics examined by Evans: national committees (to advise political institutions); research ethics committees, which ensure that research proposals adhere to certain principles; clinical ethics committees, which provide support for individual decision making; and finally, those designed to promote broader public discussion, as articulated in the UNESCO Universal Declaration on Bioethics (2005) – which some scholars believe has not yet been properly institutionalized. Like Montgomery, however, I believe that we should not limit the concept of bioethics governance to this typology, as these evolve in specific historical and institutional settings, which entails a certain diversity and contingency of emerging and existing forms: "(…) comparisons and discussions can only proceed with a schematic analysis of some sort" (Montgomery, 2016: 11).

To this end, my comparative case study aims to contribute to this kind of inquiry by including in my elaboration the historical and institutional contexts in which these ethics committees are embedded. But above all, my study is primarily interested in mapping their arguments, i.e., their modes of justification, which precisely provide explanations for their claims to legitimacy, that is, validity for their governance activities. Therefore, before proceeding with the empirical analysis, I will move on, in a last step, to briefly discuss some of the important and broader justificatory narratives within which bioethics becomes functional.

Some of these justificatory narratives have already been addressed earlier in this chapter, such as bioethics as a response to research scandals (research governance) or bioethics as a prevention of irresponsible science, a narrative that responds to the perception that science follows a technological imperative that causes public concern. In this case, bioethics becomes the mechanism for maintaining public trust. There are, however, two other broader justificatory narratives of bioethics that are of particular relevance for the upcoming analysis

and that I have so far only touched upon: "governance as a response to pluralism" and "governance as a response to relativism" (Montgomery, 2016: 17-18), both of which are clearly visible in the documents (and other articulations of these ethics committees) I have studied.

The *first* justificatory narrative begins with the problem of ***moral pluralism***, which is rooted in the fact that deep disagreements exist within a liberal democratic society. Here, the challenge is to achieve a sufficient degree of closure to allow health and research systems to function by making some sort of decision. In this context, Montgomery mentions an interesting aspect of bioethics governance, namely how competencies and thus norm-setting powers are distributed between different actors (i.e. who is actually in a position of power to create or at least co-decide such binding norms, and who is therefore also accountable to the authorities, such as parliament or courts). To maintain its legitimacy, a governance structure must allow for the possibility of disputes over issues and principles that guide such decisions:

> If bioethics governance is to be an effective response to the challenges of moral pluralism an account is therefore required of the ways its processes for mediating between conflicting factions demonstrate sufficient respect for differences to justify acting on conclusions reached. This might involve some appeal to the representativeness of the membership of governance bodies. Thus, the constitutions of some national ethics committees requires that membership includes a range of characteristics that reflect the diversity of the populations. (ibid.: 18)

In the case of the (national) Belgian Advisory Committee on Bioethics, for example, members must represent the language communities of the country, which means that a balance must be struck between French- and Dutch-speaking members. That pluralism is one of the important contexts in which bioethics operates seems clear, although this does not necessarily explain the formation of these bodies, but rather the more general forms of public debate and democratic decision-making, the author argues. Further, Evans' points out that partisan members (Evans, 2012) rather than professional bioethicists are preferred, which calls attention to the need for a robust justification for bioethics that could be able to make an ethical contribution to the ways in which pluralism is acknowledged.

The *second* interrelated justificatory narrative for bioethics governance is that it claims "(…) to move beyond a relativist assumption that all ethical opinions are entitled to equal respect" (Montgomery, 2016: 18). Market approaches as well as plebiscites are rendered insufficiently robust to govern new health technologies. Again, the *principle-based approach*, as originally developed in the US, can be seen as a response to relativism. That is, these principles act as a kind of common currency for debate in the Rawlsian sense that does not question the morality of others. Thus, no ideology, religious or non-religious, is criticized or deemed illegitimate unless it is incompatible with the very foundations of public reason in a democratic polity (this ties into the Rawlsian idea of "public reason", which is based on the idea that justification of a particular position is achieved through reasons that people from different moral and political backgrounds could accept in principle) (Montgomery, 2016; Rawls, 1999). In this regard, Montgomery states: "The study of bioethics governance might take the form of reviewing such

documentary manifestations as evidence of the content of bioethical public reason" (Montgomery, 2016: 19).

Montgomery mentions a *second* approach that such bioethics committees take to address the challenge of relativism, that is, to move from mere disagreement to some kind of normative framework without simply accepting the validity of diverse and all views in a pluralistic society. Similar to the first approach, which is concerned with identifying a set of common (or even considered universal) principles, this second approach is concerned with finding common procedural aspects of public reasoning through which its deliberations are supposed to gain legitimacy. What is emphasized, then, is the *character of the deliberative processes* that are thought to confer legitimacy on the positions reached, rather than the conceptual content (conclusions and principles of public reasoning) itself. These procedural justifications are particularly interesting in the case of the ESHRE and ASRM ethics committees.

The consensus approach and the principles of deliberation are worth mentioning as justifying procedural mechanisms for adequate public reasoning. However, another component plays a central role here, namely that all arguments must be tested for coherence and rationality and this is done based on the best available evidence and supported by careful and comprehensive analysis (ibid.).[31] Montgomery notes:

> Here the approach seeks to distinguish the resolution of disagreement through compromise and negotiation from bioethics by characterizing it as an **evidence-based** argumentative activity in which participants **must justify** and not merely assert **their positions**. (ibid.: 20; emphasis added)

This is precisely what can be observed in both cases and in the ethics reports of the two committees. However, I propose to call this a specific kind of "scientification" (or epistemologization) of bioethical argumentation (Bogner, 2021; Foucault, 1981). I want to show how this is done, albeit to different degrees, in both cases and how it manifests itself in their written ethical statements. I will also address potential problematics and trade-offs associated with this particular type of argumentative activity; namely, how the specific combination of principle-based (including human rights) and evidence-based argumentation unfolds. Moreover, what counts as evidence and is constructed as such in these ethical explanations is likewise crucial and not straightforward.

[31] See: Nuffield Council on Bioethics (2012): Strategic plan 2012-16. London: NCoB. https://www.yumpu.com/en/document/read/24828273/strategic-plan-2012-2016-nuffield-council-on-bioethics (accessed on 16th December 2019).

B. Analyzing Ethical Opinion Papers: How (Self-)Governance and Modes of Order are enacted in the Bioethics Discourse

To summarize briefly at this point: My *research interest* is shaped by the fact that I view bioethics as a particular kind of governance practice, which in turn raises a number of specific questions. ***First***, this would include, as Montgomery has pointed out, considering the people who are involved, how they are selected, the nature of authority they exercise, what are the processes, and how positions are reached (so procedural aspects how, e.g., a committee becomes assembled). ***Second***, there is the dimension of the diverse forms of *institutionalization of bioethics* and ***third***, to study exactly these *"specific literary forms of bioethics governance"* (Montgomery, 2016: 20), such as: opinions, reports, guidelines, and consensus statements. Viewing bioethics as a kind of governance practice entails to studying rather "(…) who does things, how and why they do them, than in what they study and what they conclude" (ibid.). Therefore, I decided in the course of my project to focus exactly on these *literary productions*, since they aroused my curiosity from the outset. In this regard, it is crucial to examine the logic and inner workings, so to speak, of these documents, specifically: how they are organized and structured, as well as the arguments and justifications they use to define what should be considered an *ethically (un)acceptable* practice. It is key to examine why they argue in a certain way and not in another and, especially, how they justify from their professional perspective what ethically acceptable practice should mean in one context and not in another. This also entails examining their constructions of what can count as a legitimate argument in which context. By focusing on these specific kinds of ethics committees, which are integrated into two big international scientific societies, I also study one particular form of *institutionalizing bioethics*. In this specific sense, the present cases serve to examine a particular type of governance practice: self-governance (or more narrow: self-regulation)[32] by and within this particular biomedical community through these ethic committees and their bioethical opinions. Since my aim is to understand bioethics as a governance practice, it is necessary to study precisely these particular literary forms: the ethical opinion papers of the two ethics committees of ESHRE and ASRM. Since these documents are produced in particular organizational and institutional settings, it is important to study their modes of justification, particularly how they define the boundaries of what should count as ethically acceptable practice in the context of reproductive technologies. Thus, they are also performing a specific form of organizational narrative (Czarniawska, 1997) that constitutes one of the main modes of knowing and communicating in organizations and among their membership. Investigating the capacity of such documents and the modifying work that is going on in them includes besides the making, also the non-making of issues (Asdal, 2015a: 88).

[32] I will come back to this difference, explicitly in chapter 7.4.

Chapter 5: Analysing the materiality and modes of order in bioethical opinion documents: A qualitative comparative case study

The empirical analysis centres on a qualitative comparative case study and is based on a document analysis that examines, in detail, the key *ethical opinions* of the two ethics committees of the ESHRE and the ASRM. These ethics papers could be indeed seen as kinds of strategic documents. In that sense, that they are of great importance to their societies as a whole, both in terms of their function as central positioning and justification work on controversially perceived issues in ART, and in terms of the expected impact they want to associate with these documents, namely to also address policy-makers (sometimes in an explicit way, sometimes more implicitly).

In what follows, I detail the comparative dimensions of my analysis. The primary objective here is to conceptualize the comparative approach along the main questions: *Why do a comparison, and how to compare?* Here I raise the question of what a case might mean in general, with regard to Wieviorka (Wieviorka, 1992), and how I conceptualize my case study in particular (5.1). Then, I explain the case study and the respective document corpus on which the analysis is based, as well as how and with which tools I analysed the material (5.2). Subsequently, I clarify my analytic approach in methodological terms, including drawing from Asdal's work on the document's agency (Asdal, 2015b) and the framework of pragmatist sociology put forward by Boltanski and Thévenot (Boltanski & Thévenot, 2006) of analysing how people justify acts. In the last sub-chapter (5.3), I elucidate on the other diverse materials I collected throughout, and especially at the beginning, of my research. To be better able to situate and grasp my cases – the ethics committees – I conducted a series of field visits at scientific conferences, annual meetings and online events held by these scientific societies. At these events, I had several (informal) conversations with key actors (participants and members of the ethics committees, but also with other members) and gathered a range of observational data. This has provided me with crucial background knowledge about the broader atmosphere of these scientific actors, in which the ethics committees are ultimately embedded.

5.1 Comparative issues: Why and how to compare in a case study?

How can we compare and make productive the use of comparison as a social science method? Comparison is an intricate and long-standing methodological concern in the social sciences. Because no one can avoid making comparisons in one way or another, it is meaningful to think explicitly about them, especially if one decides deliberately to use comparisons as an instructive heuristic. There have been a lot of voices, approaches and literature on them. One important aspect that I will stress right from the start with regard to Isabelle Stenger´s elaboration on "comparative relativism" (2011) is their political dimension. This raises some significant questions that have to be explicitly considered in my research: what are the arguments for comparing these two entities? What are the reasons that I have chosen specifically these two ethics committees of two international scientific societies? What could be the promising benefits of such a comparative undertaking? And finally, what allows me to compare these two

institutions, and for what reasons? Generally speaking, where do we, as researchers, take the agreement to compare particular entities? This set of questions reveals the inherent political character of comparative research work. For this, Stengers coined the notion of 'rapport' (Stengers, 2011):

> Comparison happens through what Isabelle Stengers calls the creation of 'rapport' between the entities being studied (2011: 49). This act of creation is neither a given, nor is this process ever disinterested. Our comparisons happen because of the way people, things, and organisations either smooth out or resist our progress and offer themselves up to the comparative work that we wish to do with them. (Akrich & Rabeharisoa, 2016: 140)

In Stengers's understanding, 'rapport' means a connection or relation between things that is not simply given or self-evident, but is rather something that is being actively done. In my research, 'rapport' is something I actively have created between the two cases at hand, namely by bringing them into a particular kind of conversation, into a specific relation through the different strategies and modes of my research approach, as it basically were: through specific concepts, various methods and material, and by the framing of my research question. In doing so, I brought these two ethics committees, or the numerous ethical opinion statements (which I have chosen as the core material of my analysis) in a specific kind of dialogue.

In this regard, and inspired by Akrich's and Rabeharisoa's (2016) in-depth reflection on comparative research, I would like to proceed with a few reflections on the difficulties I personally encountered in my comparative undertaking with the two selected cases. Following the two scholars, I also aimed at making sense of each case in its specificity (singularity) by creating a common atmosphere through methodology, common descriptive language, and analytical language (ibid.: 151). Maybe this reads something that is easy to do but singularizing each case by comparing it with another is quite a tricky objective. The first challenging exercise was to delineate a 'comparator', as Deville and colleagues (2016) have called it, for myself and for the reader. The comparator is an entity that does the work of comparison:

> (...) the comparator in social science is (...) not a single thing, but an assemblage of researchers, funders, and research technologies – including entities such as databases and software, legal regulations and theories, and methods. When it is put to work, the comparator creates comparison(s) by shaping and being shaped by the world [and its research subject] around it. (Deville, Guggenheim, & Hrdličková, 2016: 101)

In my case, this has been, among other things, the specific software (Atlas ti) that I used to analyze the documents in the first and second rounds of coding, before also analyzing it manually; the methods, theories and concepts I have used (some of which I have already described above and will explain further below) to make sense of this data, and which have proved helpful in seeing certain things that would not otherwise have been possible, but also, of course, in obscuring others. Furthermore, my PhD colleagues, at assorted seminars and summer schools, were part of it, as were my PhD supervisor and other research colleagues who put my analysis together with me at trial, and – of course – the object of research itself: the two ethics committees and their ethical opinion papers. The comparator is not a standard analyzer to simply be found out there but is instead something specific that develops out of the

comparative work it performs (Akrich & Rabeharisoa, 2016), and as Deville et al. put it more specifically: "(...) achieving comparison is a complex process in which a comparator has to be actively assembled" (Deville et al., 2016: 102).

After some time spent fiddling around with these methodological issues and doing this 'constant comparison' (Glaser & Strauss, 1967), which means switching from one site (or: one case) to the other and vice versa, and through that, deepening my understanding of each case in its specificity, I became unpleasantly confronted with the next intricate question that concerns another level: *how to present this comparison in writing, i.e. in a monograph*? When I started writing my dissertation, or rather, these analytical chapters (which you, dear reader, are reading now): I wondered how, for heaven's sake, to present in writing my comparison of these ethical statements from the two committees, especially when it comes to taking adequate account of the idiosyncrasies of the two committees and their work – this is indeed one of the riskiest businesses:

> As Hassenteufel (2005) rightly points out, writing a comparative article is a risky business. Either the author structures the article around a common interpretative framework and takes the risk of displaying the cases under comparison as mere illustrations of the concepts s/he puts forward, or the author details the cases s/he studies and concludes with a general discussion, an option which may undermine the comparative nature of the paper. (Akrich & Rabeharisoa, 2016: 153)

I have had to find my own way to maneuver through these two types of options and hope that I have at least satisfactorily achieved the twofold objective of drawing out their characteristics through comparison by focusing on common practices. The common practice I have chosen as the vehicle for analyzing and thus, comparing the modes of justification in their ethical opinions is precisely the act of writing such opinions. The characteristics I have attempted to highlight through my analytic lens(es) are, on the one hand, the framework of pragmatist philosophy (Boltanski & Thévenot, 2006) to focus on the *justifications* that enable them to develop legitimate positions and make decisions about what should count as an ethically acceptable practice. On the other hand, Mol's analysis of a *logic of care* and a *logic of choice* shows the extent to which the latter is still a fairly dominant logic that also structures these spaces of bioethical discourse, and not only medical practices within a hospital context. I will expand on both analytical lenses in the following chapters.
Further, I hope that I achieved my goal in following Akrich and Rabeharisoa's understanding of viewing and showing that singularizing operates as a specific mode of generalization: singularizing one's view on one case with one's view on the other case, so much so that singularizing implies a sort of generalization:[33]

> This has a crucial effect on the intellectual space we progressively designed: it is a space within which the analysis of each case is deepened through the circulation from one site to the next, thus suggesting a mode

[33] Special thanks go to Vololona Rabeharisoa who had been so kind and gave crucial comments on my research proposal in the early days of my PhD in 2017 at a seminar in Vienna at the Department for Science and Technology Studies. She pointed particularly at these dimensions of comparison in my research. This helped me a lot when rethinking my case study throughout my writing process of this comparison.

> of generalisation which does not consist of extracting a few dimensions out of the singularity of each case, but rather thickens its singularity in light of the others. (Akrich & Rabeharisoa, 2016: 152)

In this specific sense, I followed their actor-network theory understanding with its principle of symmetry, which entails treating diverse actors in a symmetrical way and that explicitly rejects predefined exogenous metrics as an analytical frame (which in their case, due to the framework of an EU project, constituted a rejection of the nation-state as a defining factor for differences). What they actually did in their study on patient organizations was to emphasize the existence of *common practices* through which each organization can be viewed and studied. To view each organization through the lenses of these common practices (the paperwork of the ethics committees in my case) has enabled me, on the one hand, to produce a dense description (Krause, 2016), and, on the other, to study exactly each committee's specificities, and by that "to deepen understandings on their singular and original way of dealing with their own problems" (Akrich & Rabeharisoa, 2016: 160). In my case, it is precisely the writing of these opinion papers and the resulting archive of these statements that constitutes a common practice between these two actors. From the very beginning, the written work of these ethics committees has attracted my attention and interest, which has to do with the fact that I came across this comprehensive (online) *'archive' of ethical opinion papers* (aside from a range of other documents) on the societies' websites. This archive is interesting insofar as it also builds a chronological trajectory in a way that can be studied: so which issues emerged and how they (dis)appeared and were modified over time was visible through their papers. From an analytical point of view, this comprehensive collection of ethics documents represents a highly interesting feature of bioethics work that is worth scrutinizing. The notion of the *archive* is further intriguing in this context, especially when following a *Foucauldian understanding of discourse*. The *'archive'* then actually constitutes a "(…) historical *apriori* of particular discursive events of an epoch while at the same time operating as a general structure that allowed these discourses to emerge in the first place" (Lemke, 2021: 97). Further:

> (…) the archive defines a particular level: that of a practice that causes a multiplicity of statements to emerge as so many regular events, as so many things to be dealt with and manipulated. (…), it reveals the rules of a practice that enables statements both to survive and to undergo regular modification. It is the general system of the formation and transformation of statements. (Foucault, 1972: 130)

In this sense, the archive as it is understood by Foucault is illuminating as "the general system of the formation and transformation of statements", which also reveals "the rules of a practice that enables statements both to survive and to undergo regular modification" (Foucault, 1972). These opinion papers as inscription devices can indeed be seen as a practice that creates – so to speak – the space which establishes and forms the rules that enable particular statements to emerge, to be repeated and modified and thus claim validity. Contextualised in a Foucauldian understanding of discourse, this collection of ethics documents (and their inner workings) establishes indeed a "system of discursivity", i.e., what can be said and how it can be said and thought about at a particular time and place in the field of assisted reproductive medicine and ethics. The core of my analysis builds on this huge document corpus of ethical opinion statements composed by these ethics committees (see chapter 5.2). The specificities of how

they deal with the issues at stake within these papers relate to how they justify medical practices and reproductive technologies. Importantly, this way of comparing comes with a different conception of generalization. Akrich and Rabeharisoa formulated it in this way in the context of their research on patient organizations:

> Rather, it was a matter of singularisation, which entailed shedding light on and making sense of how each patients' organisation construed its cause and its context (Asdal and Moser 2012) in light of how other organisations do it. Our approach towards 'how to compare' and 'what for', attempts to put an end to the prevarications between sociology and history (Wievorka 1992; Passeron and Revel 2005). (…) What we did instead was to highlight the existence of common practices amongst patients' organisations, and to examine each organisation through the lenses of these practices. This eventually enabled us to pick out each organisation's specificities, and to deepen understandings on their singular and original way of dealing with their own problems. (Akrich & Rabeharisoa, 2016: 160)

Before continuing to elaborate on justifications as my main analytical lens for this written bioethical decision-making work, I must shortly discuss framing such a comparative case study.

5.1.1 Framing comparison

At this point, I would like to discuss briefly Tereza Stöckelová´s problematization of framing a comparative research project. The author is very explicitly concerned with the political nature of such framings. Through showing the multiple hegemonic framings of EU research projects (for instance, the UK´s hegemonic position, which always was considered as a benchmark with regard to scientific excellence) she had reached the conclusion that "(…) ´research design´ issues are not simply methodological, but they simultaneously concern multiple facets of politics, including the academic one" (Stöckelová, 2016: 182). The aim of her discussion is to lead the reader´s attention to the following point: "(…) social research should strive to create investigative frictions and make comparisons that go ´against the grain´ of prevailing notions, rather than polish (however inadvertently) existing dominant realities" (ibid.: 183). This means, we cannot avoid giving our comparison(s) a framework, the aim of which should then be to make it reasonable, and this is inevitably not politically innocent in any case. In the case of my own research, some readers could expect a cross-national framework when it comes to the comparison of two same, but yet different organizations (Deville et al., 2016), which are embedded in specific socio-cultural and geopolitical environments. But framing the comparison in terms of nationality is definitely not the aim of this project. This would not be an adequate unit of comparison here. As mentioned earlier, my focus lies rather on the question of: how are medical practices with regard to reproductive technologies, medical decisions and positions are justified as ethically acceptable by these particular actors (scientific societies)? How is this done by the two committees in their ethical opinions? Here, I again follow Akrich and Rabeharisoa's understanding, which explicitly rejects a predefined exogenous metrics (here national contexts) as an analytical frame. A comparison that explicitly refuses national context as a causal explanatory framework has two sides: first, it is politically coined, in the sense of refusing the very hegemonic (EU) framework that defines some countries as advanced, whereas some others as backward. Second, it is theoretically coined, in terms of actor-network theory, the aim of which is to follow the actors themselves and their self-construed contexts and practices.

Consequently, I rather aim to focus on the diverse field comparisons (Meyer, 2016), on the worlds in the making. The idea of field comparison similarly follows a basic assumption of ANT of following the actors themselves, i.e., following their comparisons and knowledge claims (Meyer, 2016), and in my case, especially their modes of justification as central knowledge-producing devices. During my analytical work, I have followed their self-drawn contexts, their self-established connections to other institutions or to each other and, importantly, their justificatory arguments that define what should count as ethically acceptable practices or, in some cases, as unethical or not yet acceptable. In addition, because the project's goal has been to follow the organizations´ own histories, and self-descriptions, I have decided not to undertake a preselection of focus on, for instance, a specific technology (a particularly controversially perceived technology, for example). Starting from there, in my comparison, I have instead followed their own selections, which means what they themselves deem important and worth considering at any given time. Or, in other words, it is part of the empirical research and my research interest to find out and to show which documents to follow and which ones get to play a role within this particular discursive formation (Asdal & Reinertsen, 2022).

5.1.2 Case descriptions and document corpus

In what follows, I describe my case study – the two ethics committees as cases – in more detail, as well as discuss the respective organizations more generally because they form the broader environment and atmosphere in which these committees are embedded and operate.
One of the organizations is situated in Europe (ESHRE) and the other one is in the U.S. (ASRM). Both societies have special bodies that address ethical issues: in the case of ESHRE, it is currently the *Ethics Committee* (but in the past, it was called *Task Force)* that drafted the so-called *Task Force ethics and law statements*, which my analysis focuses on. Additionally, the ESHRE has a special interest group regarding ethical and legal issues that regularly organizes so-called campus events (workshops and seminars: basic as well as advanced ones) and sessions at their annual meetings. In case of the ASRM, the group is also labelled as *Ethics Committee*, which publishes their papers as *Ethics Committee opinions*. Both of these ethics working groups consist of a broad range of diverse scholars and experts: medical professionals, social scientists, philosophers and lawyers, geneticists (natural scientists), representatives from patient organizations and others, and sometimes they include external experts with special knowledge on a particular issue. The kinds of papers they publish include positions, opinion papers, recommendations and guidelines that are published in the respective journals of both societies.
Both scientific societies have a multidisciplinary and international character that is evident by their broad and diverse membership that is distributed all over the world. Regarding their membership and attendees of annual congresses, both societies hold an annual meeting, which includes joint ESHRE-ASRM exchange sessions, as well as other exchange sessions with diverse institutions and actors in the field. In addition, they jointly hold a biennial meeting, which is titled **"The best of ASRM and ESHRE"** to exchange approaches from both sides of the Atlantic.

Both societies are similar in their aims and scopes and also share strong collaborations (mutual points of references) to each other as well as to other societies in the field of (assisted) reproductive medicine. Furthermore, in their self-descriptions, both are dedicated to establishing global leadership in their field by fostering the advancement of the science and practice of reproductive medicine through education, innovative research, development and the dissemination of the highest ethical and quality standards in patient care, clinical and laboratory procedures and the harmonization in clinical practice. Their mission statements read as follows:

Mission and Vision (ESHRE) The main aim of the European Society of Human Reproduction and Embryology is to promote interest in, and understanding of, reproductive biology and medicine. ESHRE collaborates globally and advocates universal improvements in scientific research and harmonization in clinical practice. It also provides guidance that enhances safety and quality assurance in clinical and laboratory procedures. ESHRE's activities include teaching, training and professional accreditations, as well as developing and maintaining data registries. It also facilitates and disseminates research in human reproduction and embryology to the general public, scientists, clinicians and patient associations. ESHRE collaborates with politicians and policy makers throughout Europe.[34]
ASRM Mission Statement (ASRM) **Mission** The American Society for Reproductive Medicine (ASRM) is dedicated to the advancement of the science and practice of reproductive medicine. The Society accomplishes its mission through the pursuit of excellence in evidence-based life-long education and learning, through the advancement and support of innovative research, through the development and dissemination of the highest ethical and quality standards in patient care, and through advocacy on behalf of physicians and affiliated health care providers, and their patients. **Vision** The American Society for Reproductive Medicine (ASRM) will continue to be the national and international leader for multidisciplinary information, education, advocacy, and standards in reproductive medicine and science, with the goal of ensuring accessible, ethical, and quality reproductive care for every person.[35]

Table 1: Mission Statements of the ESHRE and the ASRM

Contextualizing my case study involves asking these two questions: firstly, why exactly these two cases? And secondly, what does 'case study' actually mean, and what purpose does it serve, and which insights can it provide? According to Wieviorka (1992), a case study is neither purely empirical nor purely theoretical. Rather, it is a special way of bringing theory and

[34] https://www.eshre.eu/Home/About-us/Mission-and-Vision (accessed on 24th June 2022).
[35] https://www.asrm.org/about-us/mission-statement/ (accessed on 24th June 2022).

practice together (Wieviorka, 1992: 160). As a result, a *case* indicates rather an outcome, and not necessarily a starting point of the research. I follow the classical mode within STS of conceptualizing a research project around a case study, in the sense of searching for cases as a kind of illustrative exempla. But, as it is with research, the case study is not a stable thing but changes in the course of the project (due to its empirical research and the developing connection between theory and its object of research) and cannot serve as a purely empirical example of what it was imagined to be in the beginning. Instead, as an analysis progresses, the view of the case changes and it becomes clearer what the case actually stands for as a case, which, of course, always relates to the decisions of the individual researcher: which concepts and categories to think with, which kinds of methodological decisions and interests become dominant and take the lead in the course of a project.

It has turned out to be my goal to make certain claims about how ethics functions in the context of the ethics bodies of (two international) scientific societies. This means examining ethics in the sense of how it is practiced and necessarily enacted, through argumentations and justifications of what should count as an ethically acceptable practice in their written opinions. I have started from a concrete (empirical) case in Weberian terms and have tried to illuminate it with a specific explanatory framework. A further advantage, or aim of a case study is to develop a potential "new" analytical category, an ideal type, which can function as a heuristic for handling other – similar, yet different – cases as well as the specific case (ibid.: 161). Investigating a specific practice is not about collecting suitable examples but instead learning new lessons, as Mol aptly put it:

> Good case studies inspire theory, shape ideas and shift conceptions. They do not lead to conclusions that are universally valid, but neither do they claim to do so. Instead, the lessons learned are quite specific. If one immerses oneself long enough in a case, one may get a sense of what is acceptable, desirable or called for in a particular setting. This does not mean that it is possible to predict what happens elsewhere or in new situations. (…) This is not to say that its relevance is local. A case study is of wider interest as becomes a part of a trajectory. It offers points of contrast, comparison or reference for other sites and situations. It does not tell us what to expect – or do – anywhere else, but it does suggest pertinent questions. Case studies increase our sensitivity. It is the very specificity of a meticulously studied case that allows us to unravel what remains the same and what changes from one situation to the next. (Mol, 2008: 9)

Furthermore, Wieviorka´s understanding of a case study is associated with comparative analysis in a particular way along two main arguments. Firstly, he draws a distinction between the sociological and historical conceptualization of a case study. The aim of the former consists of exploring a specific social aspect, process or mechanism of a phenomenon that one is able to explain it accordingly (so to speak, in a more general manner). In contrast, the goal of the latter is to follow the historical trajectory of a particular phenomenon, along with the question: why and how a phenomenon occurs in one place but not in another? According to Wieviorka, we should combine those two approaches when we work with case studies and he draws our attention to the *complementary part of a case study*, namely *comparative analysis*: "(…) a case becomes the opportunity to discover knowledge about how it is both specific to and representative of a larger phenomenon" (ibid.: 170). Comparison here serves two main functions: the deconstruction of a preconception and the construction of a scientific category (ibid.). The two cases – or taken together: the case study – of my PhD project, the two

committees and their numerous ethical opinions serve as such spaces, where it is possible to study exactly how it is both specific to and representative of a larger phenomenon: the rise of bioethics as a very specific kind of governance practice and discourse in the second half of the twentieth century, which serves several functions. One important one I suggest is the attempt to maintain self-regulating capacity within a respective biomedical community.

In summary, the goal of my comparative case study in bringing these viewpoints together should be not only to develop analytical categories capable of capturing the process of doing ethics within such organizations, but simultaneously paying attention to the self-descriptions of the organizations', and digging around organizing matters within these particular committees, and especially within their written ethical work. One main claim I am trying to make here is that they do so by justifying what they consider ethically acceptable in the area of ARTs. In the next sections, I will elaborate more on the characteristics and particularities of the two organizations I am studying.

5.1.2.1 The case of a European Ethics Committee: European Society of Human Reproduction and Embryology (ESHRE)

As a scientific society, ESHRE is representing a kind of supranational organization in the context of the European Union. They are concerned with harmonization issues, especially regarding EU-legislation in the case of good practice in ART and IVF-laboratories on the one hand, and embracing diversity and local conditions within European countries on the other. For instance, in a position paper from 2007 **on the EU Tissues and Cells Directive EC/2004/23,** they have stated:

> ESHRE, as the European representative society in the area of reproductive medicine, considers it to be important to work for harmonization of implementation, inspection and certification throughout EU member states. One ESHRE initiative was therefore to install the European Assisted Conception Consortium (EACC). The primary aims of the Consortium were to understand all implications of the EU Tissues and Cells Directives, to identify areas problematic to the ART community, and to provide interpretations to be used locally in all the European countries. ESHRE considers it pivotal to a successful implementation that a good dialog be established between EU, the profession and the national regulative authorities. During this process the EACC has had a key role in bringing together ART professionals and competent authorities of the EU member states. In EACC each EU member state is represented by one clinician, one embryologist and one representative of the competent authority. Non-EU member states are allowed to join for information. (ESHRE 2007: 1)[36]

ESHRE's headquarter is located in Grimbergen, Belgium and its foundation is closely related to the general development of IVF. Robert Edwards, the IVF pioneer, was one of the societies' co-founders and founding editor of the ESHRE journal:

> The idea to create the **European Society of Human Reproduction and Embryology** was first conceived in Helsinki, where Professor R.G. Edwards, from Cambridge University, and Dr. Jean Cohen, from Paris, consulted their colleagues about the need for a society that would stimulate the study and research in the

[36] Position paper (2007) on EU Tissues and cells directive 2004: https://www.eshre.eu/Europe/Position-statements (accessed on 3rd February 2023).

> field of reproductive medicine and science. Both the idea to establish such a society and the outcome of their meetings proved to be successful in many ways. After several meetings (1984) it was decided that the Society should hold its first Annual Meeting in Bonn, 1985. On that occasion the **European Society of Human Reproduction and Embryology** was officially founded as a result of a broad and lively discussion during the first Annual General Meeting where delegates from all over Europe participated in the debates. (ESHRE website)[37]

A further key driver for ESHRE's foundation was the fact that the only possibility for European scientists to publish their work and achieve international recognition was to have it presented and published in the US. Additionally, many breakthroughs, such as laparoscopy, or ovulation induction with human menopausal gonadotropins and particularly IVF, all started in Europe, but without an established forum in Europe before the early 1980s to publish about these achievements (Brown & Tarlatzis, 2005). In contrast with the US, where the American Fertility Society [the former name of the American Society of Reproductive Medicine (ASRM)] had already been organising an exceptionally successful annual meeting since 1944 and publishing a monthly journal *"Fertility and Sterility",* which remains one of the major ART journals in which researchers and clinicians from every country publish their work. However, it was not easy for European scientists to publish in those journals because of the volume of papers that flowed from their American colleagues and institutions. Taken together, this inspired Bob Edwards and Jean Cohen to organize a multidisciplinary gathering in May 1984 in Helsinki where they started to articulate their idea: "(…) of a democratically elected and governed "European" society, with its own journal, an annual meeting and training workshops which could all serve as a forum for the exchange of scientific knowledge between clinicians and scientists in Europe" (Brown & Tarlatzis, 2005: ix). Membership in ESHRE is open to all individuals active in the field of reproductive medicine and science, including medical doctors, scientists, students and support personnel (such as nurses, midwives, laboratory technicians, counsellors, psychologists, social workers and ESHRE-certified clinical embryologists). ESHRE's membership meanwhile increased from 349 (at their very beginnings) to more than 7500 members from over 110 countries, with a majority of members from Europe.[38] With this membership, ESHRE "is the largest society of its kind globally and it organizes a scientific meeting attended by around 10,000 participants each year" (see ESHRE Website).[39] The three journals published by ESHRE, *"Human Reproduction Update"*, ***"Human Reproduction"***, and *"Molecular Human Reproduction"* stand beside ***"Fertility and Sterility"*** from ASRM as some of the top journals in the field of reproductive medicine and biology. Or to put it differently and to emphasize the prominence they reached in the field of reproductive medicine and biology: "Researchers and clinicians from every continent publish in these two journals" (Thompson, 2005: 209). Furthermore, ESHRE has a range of different committees (at the moment, eleven) among them are the Executive Committee, a Special Interest Group Committee, a Publication Committee, a Committee of National Representatives and, particularly relevant for my research, an **Ethics Committee** (on which this study focuses).

[37] https://www.eshre.eu/Home/About-us/History (accessed on 20th July 2020).

[38] These numbers change quite regularly due to a rising membership, for this reason I hope I am forgiven if it is not the latest numbers.

[39] https://www.eshre.eu/Membership/About (accessed on 20th July 2020).

The **ESHRE Ethics Committee** was formed under the chairmanship of Jean Cohen in 1985. In 1989, it started its tasks of developing guidelines for the application of ART and PGD (Brown & Tarlatzis, 2005). However, in the time span from 2001 until 2014, they created a so-called **Task Force for Ethics and Law (TF)**, a group consisting of scientists and scholars from diverse backgrounds that "(…) produced a set of ethical statements on specific moral issues in the practice of ART".[40] These statements were published in the main ESHRE journal **"Human Reproduction"** after their approval by the Executive Committee of the society and all TF documents can be accessed via their website, too.[41] Now they have transformed the former TF back into an Ethics Committee with seemingly slightly different tasks and organizational structures. It produces papers about controversial ethical, social and legal issues which get published in Human Reproduction Open (the latest completely full open-access journal of the society). Most recently, there was a paper titled *"Ethics of expanded carrier screening"* open for stakeholder review on their website in August 2020, with a length of 20 pages.[42] [As of 2021, this paper is now accessible on their website via Human Reproduction Open, under the title: "The ethics of preconception expanded carrier screening in patients seeking assisted reproduction" (2021)]. The length of the paper is interesting because I realized throughout my research that the ethical statements in general have become longer, i.e., more detailed and nuanced in specific ways. Moreover, the Ethics Committee is comprised of ethicists, physicians, basic scientists/researchers and, more recently, also a patient representative and sociologist as well. For some of the TF documents, they also invited external experts with special knowledge on a particular topic to participate in the discussion, or production of the document.

Document corpus: Task Force documents on Ethics and Law (ESHRE)

Here, I provide a chronological-ordered table with an overview of the entire Task Force documents on Ethics and Law of ESHRE (in total: 23), which they produced from 2001 until 2014. On their website, they usually provide the documents starting with the most recent. For my purposes here, I reversed the chronological order to better see the sequence of issues that they engaged with.

ESHRE (European Society of Human Reproduction and Embryology): Statements by the Task Force Ethics and Law
Taskforce 1: The moral status of the pre-implantation embryo (2001)
Taskforce 2: The cryopreservation of human embryos (2001)

[40] https://www.eshre.eu/Specialty-groups/Special-Interest-Groups/Ethics-and-Law/Documents-of-the-Task-Force-Ethics-Law (accessed on 20th July 2020).
[41] In the following I provide a table with all their TF documents as well as other interesting documents in which the current ESHRE Ethics Committee was involved.
[42] https://www.eshre.eu/Guidelines-and-Legal/Guidelines/Guidelines-in-development/EthicsECS (accessed on 23rd July 2020).

Taskforce 3: Gamete and embryo donation (2002)
Taskforce 4: Stem cells (2002)
Taskforce 5: Preimplantation genetic diagnosis (2003)
Taskforce 6: Ethical issues related to multiple pregnancies in medically assisted procreation (2003)
Taskforce 7: Ethical considerations for the cryopreservation of gametes and reproductive tissues for self use (2004)
Taskforce 8: Ethics of medically assisted fertility treatment for HIV positive men and women (2004)
Taskforce 9: The application of preimplantation genetic diagnosis for human leukocyte antigen typing of embryos (2005)
ESHRE Task Force on Ethics and Law 10: Surrogacy (2005)
ESHRE Task Force on Ethics and Law 11: Posthumous assisted reproduction (2006)
ESHRE Task Force on Ethics and Law 12: Oocyte donation for non-reproductive purposes (2007)
ESHRE Task Force on Ethics and Law 13: The welfare of the child in medically assisted reproduction (2007)
ESHRE Task Force on Ethics and Law 14: Equity of access to assisted reproductive technology (2008)
ESHRE Task Force on Ethics and Law 15: Cross-border reproductive care (2008)
ESHRE Task Force on Ethics and Law 16: Providing infertility treatment in resource-poor countries (2009)

ESHRE Task Force on Ethics and Law 17: Lifestyle-related factors and access to medically assisted reproduction (2010)
ESHRE TF 18: Oocyte cryopreservation for age-related fertility loss (2012)
ESHRE Task Force on Ethics and Law 19: Intrafamilial medically assisted reproduction (2010)
ESHRE Task Force on Ethics and Law 20: Sex selection for non-medical reasons (2013)
ESHRE Task Force on Ethics and Law 21: Genetic screening of gamete donors: ethical issues (2014)
ESHRE Task Force on Ethics and Law 22: Preimplantation Genetic Diagnosis (2014)
ESHRE Task Force on Ethics and Law 23: Medically assisted reproduction in singles, lesbian and gay couples, and transsexual people (2014)
A paper published in cooperation between the SIG Ethics and Law and the SIG Safety and Quality in ART on the occasion of lifting the experimental status of egg freezing by ASRM in 2012: *- Beyond the dichotomy: a tool for distinguishing between experimental, innovative and established treatment (2013)*
A new guideline (2021) from their Ethics Committee): *-The ethics of preconception expanded carrier screening in patients seeking assisted reproduction*
A recommendation paper they published together with ESHG (European Society of Human Genetics): *- Human germline gene editing: Recommendations of ESHG and ESHRE (2018, published in the European Journal of Human Genetics, Open Access);* *- there is also a background paper: Responsible innovation in human germline gene editing. Background document to the recommendations of ESHG and ESHRE (2017)* → from time to time, they publish diff. sorts of papers together with other societies

Table 2: ESHRE Task Force Documents on Ethics and Law (chronologically ordered)

All the documents have been analyzed by means of the ATLAS.ti program, which is a software tool for analyzing qualitative data (text material) and is based on a grounded theory approach (coding paradigm). I did primarily thematic coding. After some time and several rounds of analyzing, ergo coding the documents, and as I began to recognize more and more of their structure – the inner logic – of these documents and their arguments, I very much began to focus on the argumentative modes of justification, so on how and when they argue with

scientific evidence, or the principles and the informed consent process, or a combination of the three modes. These justificatory modes I will explore later on in the next chapter (6).
The last documents in the table above (grayed out) comprise different kinds of documents, which I have not analysed in a strict sense. They have rather formed contextual material, and provided me with specific insights into how some mechanisms, like, for instance, how they draft particular papers as a response to developments in the field or at related institutions. Such papers are helpful to discern the broad area of (net)work that ESHRE and its ethics people are involved in. Additionally, such papers also provide information on the relationships they have formed and cultivated with other institutions, such as ASRM. These papers are concerned with experimental technologies, such as e.g. human germline gene editing technologies or other recent themes but which have not been published under the former TF ethics group. Other ones are documents that they have published on the occasion of special events or in special collaborations. For instance, the paper "Beyond the dichotomy: a tool for distinguishing between experimental, innovative and established treatment" (2013) was published as a response to the ASRM's Practice Committee guidelines from 2012, in which ASRM defined when a technology or procedure has to be classified as either experimental or established (in case of egg freezing, oocyte cryopreservation technology). The two SIGs (for Ethics and Law and the one for Safety and Quality in ART) from ESHRE introduced an interesting intermediate state they call or suggest classifying as 'innovative' therapies. Or another document is about the responsible use of treatment add-ons that the ESHRE ethics people have produced together with a range of other organizations in the field of ART, a so-called consensus statement.
As I said earlier, I did not include these papers systematically in my document analysis, but they informed it in many important ways as context, which enabled me to follow specific discursive strands. The main focus here lies specifically on the series of ethical position statements the ESHRE TF produced in the period between 2001 and 2014, as you can see in the table above.

5.1.2.2 The case of a US-based Ethics Committee: American Society for Reproductive Medicine (ASRM)

ASRM is likewise an international and multidisciplinary scientific society in the field of reproductive medicine. ASRM was founded by a small group of fertility experts in 1944, led by Walter Williams, M.D., who back then met in Chicago (see ASRM Website).[43] Initially, the organization was known as *'The American Society for the Study of Sterility'*. The organization's name changed twice because it was deemed to no longer fit with the society's scope and activities. The first change came in 1965 when members officially voted to change the name to *'The American Fertility Society'*, and finally its second change came in 1994 at its 50th anniversary in San Francisco where members again voted to change the name to *'The American Society of Reproductive Medicine'* as it is known today:

> Members came to a full realization that the scope of the Society had broadened to include not only investigation and treatment of infertile couples, but all aspects of reproductive endocrinology, including contraception, menopause, and the endocrine problems of puberty. (Duka & DeCherney, 1995: 222)

[43] https://www.asrm.org/about-us/history-of-asrm/ (accessed on 27th June, 2022).

ASRM's headquarters was, and to some extent still is, in Birmingham, Alabama. In 2019, however, the Society announced at its Scientific Congress & Expo that it was moving and expanding its headquarters to Washington, D.C., where it had previously opened an office in 1989:

> A full awareness of the growing importance of the federal government's involvement in reproductive medicine prompted the Society to open an office in Washington, D.C. in 1989 and to launch an active program of federal and state affairs. That same year, the Society held a symposium in Washington to educate policy-makers on progesterone. The need for a Washington presence was demonstrated quickly, for that March, a panel of Society members testified at a Congressional hearing on IVF/GIFT[44] clinics. (…) He [Wyden] termed the project "a model for cooperative efforts between government and the private sector," and called on the medical community to standardize the method of calculating success rates, develop advertising guidelines, and set professional standards for IVF/GIFT clinics. (ibid.: 205-206)

In 1985, ASRM composed its own Ethics Committee, driven "(…) in part by the regulatory vacuum, indeed a Catch-22 of a go-ahead decision from a lapsed ethics board" (Thompson, 2005: 227)of the government, which was established by Jimmy Carter's Secretary of Health, Education, and Welfare and which lapsed during Ronald Reagan's administration. The Committee's reports are published as supplements of '*Fertility and Sterility'*, the main journal of ASRM, as well as online, via the societies website (see: asrm.org). The committee is comprised of medical doctors, theologians, ethicists, lawyers, physicians, and researchers.

The society in general is structured in the following way: a board of directors (1); a range of special interest groups (SIGs) (2); diverse professional groups (3); their two committees: the *Practice Committee* that issues guidelines on relevant procedures in ART as well as the *Ethics Committee* (4); and lastly, a range of affiliated societies that make up its membership and that are specialized in particular areas of reproductive medicine (see ASRM Website).[45] These are: the Society for Assisted Reproductive Technologies (SART), the Society for Male Reproduction and Urology (SMRU), the Society for Reproductive Endocrinology and Infertility (SREI), the Society of Reproductive Biologists and Technologists (SRBT), and the Society of Reproductive Surgeons (SRS). SART for instance, was founded in 1981 and is the primary organisation of professionals dedicated to the practice of assisted reproductive technologies in the United States; almost 80% of all infertility clinics are SART member clinics.[46]

There is a difference between the US and Europe when it comes to the regulation of ART: in the US there is basically no widespread national legislation for IVF, whereas Europe is the only continent where the legal regulation of ART is widespread, although it varies quite strikingly between European countries, from restrictive to very liberal legislation. Other major countries where ART is practiced, such as India or Japan, (and indeed the US), largely rely on voluntary guidelines (Präg & Mills, 2017). Some aspects of embryo research and laboratory conditions are, if anything, regulated by federal law and there are different laws in place among the 50 US states (e.g. some states have surrogacy statutes; or other states have explicit laws

[44] Gamete intra-fallopian transfer (GIFT).

[45] https://www.asrm.org/about-us/history-of-asrm/ (accessed on 27th June, 2022).

[46] https://www.sart.org (accessed on 27th June 2022).

concerning hESC research).[47] As a result, medical guidelines play a significant role in the governance and regulation of ART. Practices in assisted reproductive medicine are primarily led by guidelines of ASRM, which implies a strong form of self-regulation in this domain in this country (Spar, 2006). A further example of this is provided by the ESHRE: „Practice is mainly led by guidelines of the ASRM (American Society of Reproductive Medicine), but all clinics are required by law to submit the data of each treatment cycle to a national registry" (ESHRE fact sheets 2, January 2017: 1).[48] It quickly becomes apparent that ASRM and its affiliated societies combine a large and powerful self-regulating medical community in the US that advocates for further advancement in science and the practice of reproductive medicine, and by that, they try to foster a crucial part in overseeing and regulating ART practices from within the professional community. Or, as ASRM has written itself on its website when describing its tangled history:

> Recognizing that government was exerting increasing influence over medicine, including its own specialty, in 1977-78, the Society moved to make its views known in policymaking circles. Its first action was to sign an agreement with the American College of Obstetricians and Gynecologists to share that organization's Washington, D.C. office. This office was intended to keep membership informed on legislative matters of importance to reproductive medicine and provide a means to make the Society's voice heard by the appropriate individuals and government agencies on matters of concern to the Society. (Duka & DeCherney, 1995: 146-148)

The creation of IVF has led to an emerging area of law and policies that is much broader and more complicated than most lawyers practicing in this area could have imagined (Niederberger et al., 2018). Furthermore:

> As IVF continued to develop, producing new reproductive possibilities never before considered, the Board of Directors of the Society charged its Ethics Committee to conduct a thorough study of these advances and report its conclusions. The result was the start of a process of ethical examination that continues to this day, and that, in its depth and duration, is probably without precedent in American medicine. (Duka & DeCherney, 1995: 187)

ASRM's genesis, how it sees the world and how it works today is very much co-produced with regard to these developments in IVF in general, and the US policy circles in particular; with their strong engagement to shape key legislation in their field, their efforts and fights for reproductive rights when public policy did not exist in reproductive matters, as well as their involvement to develop new approaches to contraception and ovulation induction they helped shape the development of IVF in America.[49]

Document corpus: Ethics Committee Opinions (ASRM)

As in the case of ESHRE, I provide a chronological-ordered table with an overview of the entire Ethics Committee Opinions from ASRM, which they have produced in the period between 2014

[47] For more details see chapter 7.4.

[48] See: https://www.eshre.eu/Press-Room/Resources; Statement 2 on "Regulation and legislation is assisted reproduction" (accessed on 27th June 2022).

[49] https://www.asrm.org/about-us/history-of-asrm/ (accessed on 27th June 2022).

and 2022, which contains, in total, 34 documents. On their website, they usually provide the documents starting with the most recent. As was done previously, it makes sense to present it in chronological order, to see the trajectory of the development of the issues. This is a particularly tricky issue in case of ASRM, because they update their ethical opinions on a regular basis. Thus, there appears to be a discrepancy between the timespans of ESHRE's and ASRM's publication dates of their ethical opinions, but this does not necessarily reflect when they engaged with an issue for the first time. ASRM's ethics committee does indicate that a paper has been updated (if a paper replaces a previous version of it) at the very beginning of every single paper, with the standard phrase: "This document replaces the previous version of this document by the same name, published in XYZ". This practice makes it is possible to see when they engaged with a subject for the first time. Further, there is also the possibility (for members) to access the older versions of papers in a comprehensive online archive on their website. This basically means that ESHRE did not start writing their ethical opinion statements much earlier, as a simple comparison of the timelines would suggest. And consequently, ASRM did not start to publish their first paper in 2014 on "informed consent and the use of gamete and embryo donation", as the list below would indicate at first glance. This particular paper, for instance, represents the replacement for an earlier version published for the first time in 2004. Further, in their approach, replacement means more of an update rather than a fundamental change: they review their ethical papers on a regular basis in the context of technology development, societal and legal change, and changes in attitude that might occur within the medical community towards ethical issues in ART. This is especially notable in the case of issues around same-sex reproduction or transgender care. The way that Western societies started to discuss and reframe issues around the LGBTQIA+ community has changed quite fundamentally within the last few decades and these changes do not leave the medical discourse, its community, and medical therapies unaffected. It is frequently not only a single issue but instead an amalgam of things that lead to the replacement of a paper: scientific advances (e.g. treatment possibilities and access for transgender persons) often goes hand in hand with socio-political developments (e.g. transgender rights). In STS-terms, we would say that these updates are co-produced because technoscience and society are closely entangled, all of which makes a reconsideration of an issue and a respective replacement necessary. This replacement practice represents a striking difference between the two committee's approaches to their work and is indeed an interesting feature of ASRM's work in ethical decision-making.[50]

[50] Recently, however, ESHRE has published on its website that its Ethics Committee has initiated to review all TF documents (as the papers seem to be outdated in some respects). On the one hand, this represents an approximation towards the ASRM's approach of regularly updating their papers, but on the other hand, it shows likewise that the positions they reach with respect to the issues at stake are subject to temporal and socio-technical changes (see here: https://www.eshre.eu/Specialty-groups/Special-Interest-Groups/Ethics-and-Law/Documents-of-the-Task-Force-Ethics-Law (accessed on 4th June 2023)).

ASRM (American Society for Reproductive Medicine) Ethics Committee Opinions
Informed consent and the use of gametes and embryos for research: a committee opinion (2014)
Defining embryo donation: an Ethics Committee opinion (2016)
Disclosure of medical errors involving gametes and embryos: an Ethics Committee opinion (2016)
Financial ‘‘risk-sharing’’ or refund programs in assisted reproduction: an Ethics Committee opinion (2016)
Oocyte or embryo donation to women of advanced reproductive age: an Ethics Committee opinion (2016)
Transferring embryos with genetic anomalies detected in preimplantation testing: an Ethics Committee Opinion (2017)
Using family members as gamete donors or gestational carriers (2017)
Child-rearing ability and the provision of fertility services: an Ethics Committee opinion (2017)
Informing offspring of their conception by gamete or embryo donation: an Ethics Committee opinion (2018)
Posthumous retrieval and use of gametes or embryos: an Ethics Committee opinion (2018)
Use of preimplantation genetic testing for monogenic defects (PGT-M) for adult-onset conditions: an Ethics Committee opinion (2018)
Fertility preservation and reproduction in patients facing gonadotoxic therapies: an Ethics Committee opinion (2018)
Ethical obligations in fertility treatment when intimate partners withhold information from each other: an Ethics Committee opinion (2018)

Disclosure of sex when incidentally revealed as part of preimplantation genetic testing (PGT): an Ethics Committee opinion (2018)
Planned oocyte cryopreservation for women seeking to preserve future reproductive potential: an Ethics Committee opinion (2018)
Misconduct in third-party assisted reproduction: an Ethics Committee opinion (2018)
Consideration of the gestational carrier: an Ethics Committee opinion (2018)
Interests, obligations, and rights in gamete and embryo donation: an Ethics Committee opinion (2019)
Fertility treatment when the prognosis is very poor or futile: an Ethics Committee opinion (2019)
Compassionate transfer: patient requests for embryo transfer for nonreproductive purposes (2019)
Ethics in embryo research: a position statement by the ASRM Ethics in Embryo Research Task Force and the ASRM Ethics Committee (2020)
Human immunodeficiency virus and infertility treatment: an Ethics Committee opinion (2021)
Access to fertility services by transgender and nonbinary persons: an Ethics Committee opinion (2021)
Disposition of unclaimed embryos: an Ethics Committee opinion (2021)
Disparities in access to effective treatment for infertility in the United States: an Ethics Committee opinion (2021)
Moving innovation to practice: an Ethics Committee opinion (2021)
Financial compensation of oocyte donors: an Ethics Committee opinion (2021)

Access to fertility treatment irrespective of marital status, sexual orientation, or gender identity: an Ethics Committee opinion (2021)
Ethical issues in oocyte banking for nonautologous use: an Ethics Committee opinion (2021)
Provision of fertility services for women at increased risk of complications during fertility treatment or pregnancy: an Ethics Committee opinion (2022)
Use of reproductive technology for sex selection for nonmedical reasons: an Ethics Committee opinion (2022)
Reproductive and infertility care in times of public health crises: an Ethics Committee opinion (2022)
Updated terminology for gamete and embryo donors: directed (identified) to replace ‘‘known’’ and nonidentified to replace ‘‘anonymous’’: a committee opinion (2022)
Cross-border reproductive care: an Ethics Committee opinion (2022)

Table 3: ASRM Ethics Committee Opinions (chronologically ordered)

All documents have been likewise analyzed by means of the ATLAS.ti program. I did primarily thematic coding as in the case of ESHRE's papers. After some time and several rounds of analyzing, ergo coding the documents, I came to very much focus on the three argumentative modes of justification, so on how and when they argue with scientific evidence, or with principles and the informed consent procedure. In the case of ASRM, informed consent constitutes a very prominent justificatory argument when it comes to justifying a practice or technology as ethically acceptable. I also looked for how those three modes become combined in specific ways, or in which way and part of the opinion statements they are introduced to justify what and which kinds of arguments are made.

5.2 Analysing documents and modes of justification in bioethical opinion papers

The reason why it is important to direct the analysis and attention towards such written bioethical statements is due to the fact that these documents want to convince with their contents and form. Following a Foucauldian understanding of discourse implies understanding these documents as practices that systematically form the objects of which they speak. I view these written statements as a particular practice and form of bioethical discourse, namely, as a (soft) mode of governance inasmuch as they formulate and establish rules, interpretations, justifications and arguments for defining ethically acceptable practice in the domain of

reproductive technologies. By viewing these documents in this way, they can be understood as kinds of inscription devices. As such, they fulfill their function as a governance instrument, precisely because of their characteristic of providing and constraining interpretation. Understood in this way, these documents then lead us to the question of which kinds of contexts, framings, and weavings get construed in which ways, where different things (such as human actors, biological entities, technologies, procedures and therapies, moral values) become specifically ordered, assembled, and located in space and time. I argue that this is done through certain modes of argumentation, that is, through the justification of medical acts and technologies as legitimate forms of medical practice, and through which certain issues are enacted in the first place because the very act of justification allows certain statements to occur and claim validity.

And as they partly indicate within these papers, those opinion documents are imagined to form the potential basis for public policy. For instance, back then, the ESHRE TF indicated in one of their papers regarding the issue of sex selection for non-medical reasons in Western societies: "Others are less convinced about this or regard this type of argument as again too speculative to serve as a basis for public policy" (ESHRE TF 20, 2013: 3-4). Consequently, they consider indeed the types of arguments they put forward in terms of functioning as 'proper', meaning legitimate, accepted forms of justifications in policy circles. Not every argument might function as a reasonable justificatory argument when leaving the scientific and ethical sphere and becoming a political one.

Before moving on with explaining my methodological lens towards these documents as lively (value) agents and technologies of politics, I would like to make a short detour to discuss the naming of these *ethics papers,* because both of the committees have their own 'names' or 'designations'. While ESHRE has called their papers "***Statements by the Task Force Ethics and Law",***[51] ASRM, in contrast, labels them as ***"Ethics committee opinions"***.[52] Although, I refer to them in the following most of the times by the generic name of 'ethical opinion papers' (but also alternating between statements, documents, reports) for reasons of legibility and simplicity in writing, the particular naming of these papers is worth taking a closer look at. These names already allow for the recognition of some of the subtle differences between the two committees and their approach towards dealing with 'bioethical' issues in assisted reproductive medicine. ESHRE, for instance, has also the notion of 'law' included in the title of its papers (in form of the former Task Force name), which suggests that its contexts are more than simply an opinion. Obviously, ethics and law are two aspects that, in their conceptualization, go together closely in the case of ART, which seems to suggest an important aspect in terms of self-regulation. I propose that there is indeed a difference between calling a paper an 'opinion' or a 'statement'. An opinion (ASRM's choice) evokes to an extent rather an association with a (non-binding) interpretation (and further, one possibility amongst many),

[51] See here: https://www.eshre.eu/Specialty-groups/Special-Interest-Groups/Ethics-and-Law/Documents-of-the-Task-Force-Ethics-Law (accessed on 15th April 2021).

[52] See here: https://www.asrm.org/news-and-publications/ethics-committee-documents/ (accessed on 15th April 2021).

a value judgment, or a belief, so something specific or situated. The Merriam-Webster dictionary defines "opinion" as *"a view, judgment, or appraisal formed in the mind about a particular matter"*.[53] Whereas a statement (ESHRE's use) indicates a slight connotation with a remark or declaration, which of course can be also something loose, but it evokes much more a closeness to facts, or at least that it is based on something more than a belief, thus, something more official or formal. In the same dictionary the notion of "statement" is defined as *"something stated: such as a: a single declaration or remark: assertion, b: a report of facts or opinions"*.[54] Obviously, these are rather subtle distinctions that might also be traced back to socio-cultural aspects how to approach delicate topics such as ethical issues in reproductive medicine, which are often framed as controversial. The supplementary of ***'law'*** is also an interesting add-on in the case of ESHRE, which emphasizes that the society sees its own role (or how the TF for ethics and law saw their role) to consider the issues in ART not just for one country, but in the broader context of a variety of European countries with a plurality of national medical legislations in this area. This is clearly co-constituting the situation, so the way one thinks about the ethics and politics of ART. However, one important difference can be pointed out here, specifically the difference between *ethics* as a kind of rule-setting practice, which implies rather a compliance with a rule or rules (in the plural) which are guiding actions; this is in contrast to the *law*, which operates and is based on prohibitions. Ethical statements obviously have a lot to do with this kind of rule-making practice, and in a sense represent such a space in which rules, or their basis, are established through the specific form of definitional, ergo justificatory, work that they perform when it comes to what is to be considered ethically (un)acceptable practice.

A further dimension entails that ESHRE's ethical positions and the recommendations attached to them could easily stand at odds with different domestic laws in this area; therefore, they also have to acknowledge the legislative multiplicity that exist within their bioethical considerations in one or another way. This means, one will often find sentences like this in their ethics statements: "… but practitioners have to be aware of the respective legal situation in their home countries when offering XYZ". For EHSRE, it is crucial to emphasize the importance of the legal situation(s) because they do not aim, or are not in the authoritative position to contravene domestic medical regulations in ART. But what they can do instead is to formulate their expert view, including rules, in form of recommendations, which they deem relevant to implement, to change, or to (re-)consider in light of scientific advances and new technological developments in this field.

ASRM likewise mentions legislation in context of the US, which refers mainly to federal and state law. They often mention legal issues related to particularly controversial topics, such as stem cell research and human embryo research.

Both committees have to find their own ways to deal with these local legal differences, but in the case of ESHRE this also gets evident in the naming of these ethical statements. However, both societies see the need to link these two aspects together: ethics and law. At the end of Chapter 7, I will bring my analysis back to the question of (self-)governance (or: self-

[53] See: https://www.merriam-webster.com/dictionary/opinion#learn-more (accessed on 20th April 2022).
[54] See: https://www.merriam-webster.com/dictionary/statement#learn-more (accessed on 20th April 2022).

regulation),[55] including the capacity of these documents to function as important instruments for such a self-regulating medical community.

However, before elaborating further on this and other related aspects, I will introduce some conceptual thoughts on how to consider and handle these specific documents analytically.

5.2.1 The work and functions of documents

First, I will elaborate on Kristin Asdal's understanding of documents as tools of politics. Asdal claims that (policy or other strategic) documents are involved in enacting and 'co-modifying' issues, so they are lively value agents (Asdal, 2015b). In a further step, I will outline my analytical stance when it comes to the analysis of justifications, or justificatory arguments. In this regard, I draw upon pragmatist philosophy in the style of the French sociologists Boltanski and Thévenot (2006). Their approach is concerned with the analysis of how actors reflexively do different types of 'justification work', criticizing or justifying particular orders of worth in specific situations (Boltanski & Thévenot, 2006; Jagd, 2011). So, my aim, similar to theirs, is to study how people justify: in my case study, I ask how experts in these ethics committees justify medical and research practices as ethically acceptable (or sometimes as unacceptable) from their professional point of view in and through these particular literary productions, namely their ethical opinions and how to classify this work in a broader discourse around these issues. Documents are indeed lively agents through which their authors try to produce some kind of commitment, indicate a particular choice over others, signal preferences and standards, and consequently a particular way of dealing with, and thus ordering and governing, parts of social life, or even a specific phenomenon which is considered in a respective document. Likewise, the committees delineate in a way the standards of justificatory arguments in these papers:

> Standards' ubiquity gives them an obvious character, but it is exactly this obviousness that sociologists should critically interrogate. Just as the choice of one standard over another signals a preference for a specific logic and set of priorities, so the choice of standards of any sort implies one way of regulating and coordinating social life at the expense of alternative modes. When examining the emergence of standards in new and varied domains, sociologists need to ask how social life became organized through these specific standards as well as how it could have been done differently. (Timmermans & Epstein, 2010: 85)

A document, especially these committee opinions, should not be considered as a strict standard in the sense of Timmermans and Epstein; nevertheless, I would propose to viewing it as a kind of soft governance tool, or indeed, as an inscription device in the way of setting and (re)drafting standards and inscribing particular interpretative frameworks (about visions how to deal with ARTs in the present and future), but also by defining actors and their tasks (Callon, 1984). Kristin Asdal intensively engaged with the work of documents and succinctly pointed out:

> (…) documents are technologies of politics (Asdal 2004, 2008) or, as I will elaborate on them here, innovation devices for valuing and timing values. This implies that rather than simply representing and being a source of an extra textual reality with the 'real practices' taking place elsewhere, the documents can be understood as lively value agents. (Asdal, 2015a: 169)

[55] I will return to this difference in the course of Chapter 7.

The author conceptualizes these particular kinds of dissemination (in the quote here, a Norwegian policy document on industrial pollution) as value generators in their own right, which are involved in enacting and 'co-modifying' issues. Her main interest leads to the question: "How do issues, political matters, emerge and get to have political effects and consequences?" and further: "When it comes down to what is at issue, the res – the case – that creates a public around it, political philosophy is much too silent. But, one might ask, what is an issue in the first place? How do scientific and technical entities or objects become issues?" (Asdal, 2008: 12-13). This means, ***issues and publics*** are coproduced in specific ways, and that they are not naturally given entities; instead, they have to be made in the first place (e.g. Felt & Fochler, 2010; Marres, 2005). Furthermore, this draws our attention to the transformative capacity of documents. Asdal's reflections are mainly based on the assumptions of ANT, as well as Foucault's understanding of discourse, which reads as follows:

> Words and things' is the entirely serious title of a problem; it is the ironic title of a work that modifies its own form, displaces its own data, and reveals, at the end of the day, a quite different task. A task that consists of not – of no longer – treating discourses as groups of signs (signifying elements referring to contents or representations) but as practices that systematically form the objects of which they speak. (Foucault, 1972: 49)

Following Foucault, her interest lies precisely on this entanglement of words and things. Consequently, based on these assumptions, one can read such documents as lively actors (and indeed as inscription devices in Akrich's sense) that are not just representing some reality out there, something that happens somewhere outside, or behind the text (so to speak, in a non-linguistic reality), but she addresses precisely the text-body and its enactments itself and how contexts are playing into, take part in, and are modified by and through the text as a thing itself (Asdal, 2012). Therefore, her reflections in "Contexts in Action …" also remind us quite nicely that 'con-text' has obviously something to do with text – the situative and surrounding text in which an utterance can happen:

> "Text" comes from the Latin texere, meaning to weave, and context derives from contexere, meaning to weave together or to weave with (Janssen 1985). Context then can rather be seen as that with which a text is woven together. The strategy then, I argue, is simply to begin tracing such weavings. The place from where we ought to start is the relevant text in question, and to take what that text utters literally. In doing this, we need to bear in mind that contexts, situations or that which we from an actor-network perspective could also call collectives do not always come in the singular. As I will aim to demonstrate through the case below, radically conflicting contexts may interact within a text and together produce an issue, a concern, a sensibility – hence, a particular situation. (ibid.: 388)

For instance, in the case of ESHRE's first TF document on the in-vitro-, or pre-implantation embryo, they define an embryo as a biological entity by explaining the different biological sequences of its development (reflecting the in-vivo events). Simultaneously, an embryo acquires a moral value since it is thought of in relation to society and humankind more broadly "(…) it is human and deserves our respect as a symbol of future human life" (see ESHRE TF 1, 2001: 1046-47) that has to be considered in all kinds of ART procedures. This means they contextualize it in a specific manner through which a very specific issue emerges: the

controversial nature of this 'new' entity. Furthermore, they continue, "The semantic variations in legal definition of the embryo are a reflection of the principled arguments concerning this entity" which are summarized in the further course of the document (see ESHRE TF 1, 2001: 1046-47). Different legal definitions of the embryo reflect cultural imaginations and ideas of life, and specifically, when it starts and ends, which is reflected in this excerpt from the same ESHRE document:

> German law defines the entity as 'the fertilized human egg cell capable of development, from the moment of fusion of the pronuclei', while in Spanish law the pre-embryo (the group of cells resulting from the fertilization of ovum until the implantation and formation of the primitive streak) is distinguished from the embryo (process of organ formation) and the fetus. (ESHRE TF 1, 2001: 1047)

The question of *when does life start* is dissolved by the German lawmaker in a rather obviously Christian manner, as one can notice from the quote: life starts with procreation, with the fusion of the oocyte and sperm. However, the same question remains mainly undissolved and undefined in the US context for both foetuses and embryos, as one can observe in the ongoing abortion debate. Whereas Spanish law introduces a scientific/technical difference between the various stages of the embryo in biological terms (similar to EHSRE), which implies that the transition from the embryo to foetus is also a matter of terminology, which becomes formed as an object in this very scientific and legal discourse.

If one aims to understand *bioethics* as a *governance practice*, it is necessary to examine precisely these literary forms. Since these documents are produced in particular organizational and institutional settings, it is important to ask not only about the modes of justification, and how they consider particular practices and technologies as ethically and morally acceptable, or just the opposite (which is the rare case), but also the con-texts in which those justified practices (become) embedded, and more importantly, what these writing practices mean in terms of self-regulation to keep the power of medical decision-making through ethics within their own ranks.[56]

Investigating the capacity of such documents and the modifying work that is going on in them includes both the making and the non-making of issues (Asdal, 2015a: 88). Furthermore, as Stark has emphasised: "(…) formal documents always provide an idiosyncratic version of past events and of potential future actions despite the deceptively objective, authorless style of most official record" (Stark, 2011: 59). It is the very constitutive perspective of the documents that I am interested in, of how they are constituting social actors, issues, and moral truths. In this context, it is also interesting to examine whether, and if so, how they represent (dis)agreement, consensus, or other deliberative statements, when they represent, for example, two (or a plurality) of perspectives on particular issues, and by extension, how they position themselves as an overall organization, because this is a primary mandate of these ethics working groups. When the objective is to reach a sense of what these documents are doing and making, in the sense of their functions (as soft tools of governance) and in terms of their discursive materiality, it is necessary to look at how they are actively making and modifying issues by ways of producing ethically justifiable arguments, and thus, moral truths.

[56] This will be primarily thematic in chapter 7.4.

In the next sub-chapter, I will therefore turn my gaze to these documents as argumentative spaces in which they put forward certain kinds of justifications through which the issues at stake are co-produced and indeed modified.

5.2.2 The argumentative spaces of ethical opinion papers: Modes of justification

When it comes to the internal logic and workings of these papers, I partially follow the French research agenda put forward by Boltanski and Thévenot in the tradition of pragmatist sociology in order to analyze the justificatory work that is being enacted by the two ethics committees in their written opinion papers. Particularly relevant for me is this passage:

> Entering the issue by the situated judgment leads to the modification of the theoretical models and to the taking into consideration of, notably, the question of how conventional clues are developed and how common objects are qualified. Justification relies on these operations. (Boltanski & Thévenot, 2000: 216)

In my project, this perspective is valuable because it focuses on the understanding of the dynamics of action in the broadest sense, and in a narrower sense, on understanding those actions in which actors try to come to a common agreement, i.e., it does not cover all kinds of action (Boltanski & Thévenot, 2000; Jagd, 2011). This is a helpful **practice approach** to think within the case of bioethics and its literary productions because it allows one to focus on both: agreements and disagreements. Their notion of 'pragmatic' refers primarily to linguistic pragmatics, "(…) stressing the actors' use of grammatical resources facing situations in which they find themselves (Boltanski, 2006)" (Jagd, 2011: 345). I refer to Jagd in this instance because he provides a useful elaboration on older literature by these two French sociologists that, to my knowledge, has not yet been translated. Furthermore, he offers a good overview of empirical research on organizations that used the 'orders of worth' framework in different ways:

> Pragmatic sociology (…) aims to study critique as part of actors' competencies with the aim of developing a pragmatic sociology of critique (Boltanski, 2009b). For pragmatic sociology, empirical studies of disputes involving questions of justification constitute a starting point for studying action. (…) The actors are active, not passive, and the social worlds does not appear as a place of a domination suffered passively and unconsciously but more like a space intersected by a multitude of disputes, critiques, disagreements and attempts to produce fragile local agreements. Pragmatic sociology is concerned with the analysis of how actors reflexively do different types of 'justification work' criticizing or justifying particular orders of worth in specific situations (Boltanski, 2009b). (ibid.: 346)

The inventors' particular aim had been to analyze the justification of acts, i.e. the diverse processes of justification. For this purpose, they developed six dominant orders of worth, such as the civic, market, industrial, domestic, fame, and inspired one, to which different justificatory acts can be assigned (Boltanski & Thévenot, 2006). However, these six orders of worth they developed are not so much of interest in the context of my research, but rather its particular focus on *justificatory work*, in my case, within specific organizations*, or institutional settings, i.e., the ethics committees of scientific societies*. Similarly, to the author of the review, it is key to explicitly concentrate on the complex processes involved in such justificatory work (including

critiques or attempts to produce compromises in organizations). This is important for my case because, the committees that I study are part of two bigger scientific societies, whose designated aim is to develop common positions that are representative of those societies as a whole. Furthermore, Jagd has also expressed the concern that maybe not all empirical data fits the six (or more, according to new scholarship) orders of worth particularly well and raises the question: "Does the strength of this framework lead to a relative blindness towards forms of justification that do not fit into these categories?" (Jagd, 2011: 355). Thus, it is crucial to stress the *relevance of focusing on justifications as an analytical unit as such*:

> Entering the matter through 'institutions' tends to limit each specification [of the just] to a particular community, to fellows that are caught in the same system of rules. We rather searched for an elementary unit of analysis that would not be an institution, but a **mode of justification**. Institutions and organizations were then treated as arrangements of different kinds that necessitate the integration of a plurality of imperatives. (Boltanski & Thévenot, 2000: 225; emphasis added)

Against this backdrop, my focus lies on the different argumentative *modes of justification*, which are introduced by the two actors to justify whether a medical or research practice in ART should count as ethically (and by that quite often: morally) acceptable practice from the organization's or committee's point of view or not. They are doing this by grounding their positions mainly on the following justificatory arguments: *scientific evidence, principles,* and the *informed consent* (for more details, see Chapter 6). I also looked for how these argumentative modes are combined in specific ways, or in which sequence they are introduced into a position statement, as well as which kinds of arguments are made with which particular one, alone and in combination and different variations. Focusing on the various justificatory arguments and the special role of *empirical evidence*, which can indeed function as a crucial adjudicator in deciding on and constructing what should or should not count as ethically acceptable practice (as I will show in Chapter 6). Besides that I will also look at some procedural mechanisms of justification when it comes to the committees' work, including, e.g., how the committees are assembled and their particular rules of deliberation. But the main aim is to show how powerfully questions of ethics become tied to questions of empirical evidence, and how this is done within these opinion papers.

How are different actors, objects, technological procedures, rights and principles (such as autonomy or justice) balanced against each other and thus, enacted by the different introduced modes of justification? Who speaks about whom? Or for whom is this meant to belong and be written? How and when do they use principle-based argumentation, and when do they use an evidence-based one, or even a practice-oriented approach, the informed consent? Further, what is the particular role of empirical evidence in such ethical evaluations? Is there a hierarchy of evidences at play – one that counts for more in its impact as a decision-making tool and one that counts for less? These are all relevant questions for my case study.

Because this is a critical point, I have to explicate the notion of ***'modes of justification'*** in more detail. I use the notion of 'modes' instead of 'logics' (e.g. Annemarie Mol's choice when speaking about healthcare logics), or the notion of 'orders of worth' (as Boltanski and Thévenot and others have done) because of the plurality implicated by this notion. Mol, for instance,

clarifies in her studies that the notion of **'modes (of ordering)'** makes discourses multiple and mobile:

> 'Modes' is plural: it invites a comparison of different ways of thinking and acting that coexist in a single time and place. 'Ordering', derived from the verb rather than the noun, calls up a process: it suggests that the activity of ordering involves a continuous effort, and that it may always fail. (Mol, 2008: 9)

This notion further invites a comparison between different ways of thinking and acting that coexist in a single time and place. I am particularly interested in the relations that these modes of justification establish, relations which potentially provide guidance for action and regulation on different levels (i.e. within a practical context: clinic, center, doctors practice, scientific organization, as well as policy context). Therefore, it makes perfect sense to speak about *"modes of justification"* as *ordering practice*, i.e. those are making discourses multiple and mobile, describing an ordering (governing) process (structuring), which involves a continuous effort which may always fail (ibid). The justificatory work that the two ethics committees are doing constitutes such an ordering practice because they arrange the 'ethical acceptance' of a technology or practice (making a governable issue) along the kinds of conditions it can be justified, assessed and evaluated.
These ethical opinions perform a very specific function and role within these organizations by elaborating and defining with different justificatory arguments what should count as ethically acceptable practice and what should not; who has a say and who does not in these papers; which justificatory arguments are used and preferred for which questions; which kinds of people or actors (including non-humans, such as technologies …) are considered in which ways; how is consensus or compromise reached, and how do disagreements unfold in these papers and how this is done discursively. These kinds of arrangements or agreements, such as compromise, local and temporary arrangements, or clarifications, are interesting nodes because one can analyze the different ways of reconciling various modes of justification. In his review, Jagd has likewise emphasized that different types of organizations may also be seen as devices for designing specific kinds of agreements and compromises.

Hence, my concern lies exactly in the ways in which socio-material orderings come into being and establish themselves through these papers and also with the potential power involved in that process. This perspective can be ideally combined with my focus on the involved *governance question*, i.e. with my interest in the steering effects and impacts of those ethics committees and their ethics papers by analyzing the ways of arguing and justifying what should count as an ethically acceptable practice. I focus on the complex *processes of justificatory work* done in their written ethics work, which is embedded within this wider institutional environment of particular scientific societies. Investigating these aspects of organizations may also resonate with other work focusing on institutions and organizations. Thus, my primary focus lies on the exploration of argumentative justifications (as discursive acts) in (bio)ethical opinion papers developed by these internal ethics committees.

5.3 Situating my research: Extending the feeling for the case study

The objective of qualitative comparison in the social sciences is to understand a case, or rather cases, in both their specificity and generality by producing a dense description: by travelling from one site to the next and back again, and in so doing enriching one's view on each case with the view from the other, as much as that singularizing implies a sort of generalization. In my case, this included different sites and materials. Besides the core of my document analysis studying the diverse argumentative justifications in their ethical opinion papers, I also gathered a variety of *other* ***materials***. Particularly at the beginning of my research, it was important to get a general feeling for the environment of the entire organization in which these ethics committees and their literary productions are embedded. To begin my research, I first conducted a series of field visits and informal conversations (observational data from conferences, annual meetings and online events). This has provided me with important background knowledge about the broader environment of these scientific societies in which the committees are embedded. I was interested in knowing more about their structure, scope, and membership as well as the events they organize. This is the reason why I visited a number of ***scientific events*** that had been organized by ESHRE, particularly in the period between 2016 and 2019.

As already mentioned in the case description above, both societies hold an annual meeting (AM), and at each AM, a session of the other society on a particular topic is also organized. Therefore, I decided not to travel extra to the US to an ASRM AM because this would have added too many expanses to a rather small PhD budget. Instead, I visited instead three AMs of ESHRE. There, I had plenty of opportunities to listen to members of ASRM as well, because they organized sessions at these events, too. It was possible to have *conversations* with a range of members of both of the societies at these events.

The annual meetings include different formats, such as conventional session formats with 4-5 presentations with a Q/A session afterwards, poster sessions, an exhibition hall with products and their representatives, networking events and pre-congress courses. During the three years I visited them, minor "changes" also occurred. The EHSRE ethics people, for instance, began to organize an ethics counsel session, a kind of dedicated and private Q&A session for which practitioners could sign up in advance with a case description they would like to discuss. That means, in effect, these 'ethics counsel hours' were meant to discuss with medical professionals' concrete cases (scenarios) that they had encountered in their clinics and found, perhaps, especially complex or challenging. At these annual meetings, I participated primarily in the ethics sessions but also, to a smaller extent, in others, such as medical, or clinical ones, or from the psychology counseling people, or sessions that were organized by patient representatives. Surprisingly, I came to realize that the poster sessions were particularly interesting because they are structured along a shorter input (between 5—10 minutes presentation) and then each presentation was followed by a more interactive discussion (and not a conventional Q&A part). This had simply to do with the fact that people are already standing together around a poster and not, as in a normal session, sitting in a conference room where the presenter is standing on a desk and the listeners are sitting in the audience.

I visited the following events:

- In September 2016: I visited the ESHRE Campus symposium on: "Novel gamete manipulation technologies in ART: SEEM (safety, ethical, efficient, moral) okay?", in the Netherlands, Amsterdam.
- In October 2016: a Basic training course "For infertility counselling: from theory to practice", in Vienna.
- In July 2017: ESHRE Annual Meeting in Geneva (focus of the ethics session was on „transgenderism and reproduction: state of the art in fertility options for transgender and people with sex reassignment).
- In July 2018: ESHRE Annual Meeting in Barcelona (focus of the ethics session was on "surrogacy: a gift with consequence", as well as "egg donation: medical, psychological, and ethical considerations").
- In June 2019: ESHRE Annual Meeting in Vienna (focus of the ethics session organized together with the SIG "global and sociocultural aspects of infertility" was on: "global access to assisted reproductive technologies: hurdles and opportunities").[57]

Here it was interesting to observe how experts present, discuss and handle such issues in formats other than an ethical opinion statement. Furthermore, these events were exciting places to get an overall impression of the community and its diverse membership. I had the opportunity to listen to and talk with medical professionals, embryologists, psychologists and geneticists to get a much broader impression of the manifold topics and professionals in the interdisciplinary field of ART. At these events, I also conducted a range of informal conversations with experts from these societies, particularly the 'ethics' people from EHSRE. When it comes to ASRM in particular, I participated in the exchange sessions they organized at the EHSRE annual meetings. Additionally, they run their own podcast, which produces a range of interesting episodes on current issues through personal interviews or expert discussions with members. Just to mention a few relevant examples:

- Podcast (2021): "Spotlight on the ASRM Ethics Committee: with Dr. Sigal Klipstein (chair)". In this episode, one can listen to an interview with the chair of the ASRM Ethics Committee, Dr. Sigal Klipstein, about the history of the Committee and how documents are produced for publication, which can be listened to here, e.g.: http://asrmtoday.org/srm-today-spotlight-on-the-asrm-ethics-committee-with-dr-sigal-klipstein (accessed on 24th August 2022).
- Podcast (2022): "ASRM Policy matters: advocacy, PACS [political action committee] and ASRM". On this episode they discuss current Advocacy and PACS as it relates to ASRM with Sean Tipton and Sarah Bogdan, which can be listened to here, e.g.:

[57] You can find these events on the ESHRE Website: www.Eshre.eu; however, since most of them are lying in the past it is difficult to access the archive and materials without being a member of ESHRE. This is in case of both societies normally a service just provided to members.

http://asrmtoday.org/asrm-policy-matters-advocacy-pacs-and-asrm (accessed on 24th August 2022).

- Podcast (2021): "Inside the ASRM Practice Committee with Dr. Alan Penzias". In this episode they interview Dr. Alan Penzias, the chair of the ASRM Practice Committee, who gives insights into how the committee works, which can be listened to here: http://asrmtoday.org/asrm-today-inside-the-asrm-practice-committee-with-dr-alan-penzias) (accessed on 24th August 2022).

These podcasts and other webinars provide useful background information on how the society and its committees perform to work and how they are assembled, i.e., who actually participates in which ways, or how members are involved; further, how documents are produced for publication, which also concerns the topic choice, the document's scope, and the process of document production, including how different membership is involved in their production, for instance, through an open review process. These are interesting performances of what they consider crucial and interesting to provide insights to their members and the public.

In summary, in this chapter I have set out my analytical understanding of a comparative case study by outlining the materials on which my comparative analysis is based and the important methodological threads I have followed. In addition to the Foucauldian understanding of discourse, I have opted for an ANT-based lens on documents proposed mainly by Asdal, but also by other scholars in the field of STS. As far as the analysis of written ethical statements is concerned, I draw on the justificatory analysis of Boltanski and Thévenot.

Before continuing with the detailed justification analysis, I would like to remind the reader of my research questions: 1) How do their ethics committees construe and justify what they deem as ethically (un)acceptable practices and morally justifiable decisions and positions in the field of medically assisted reproduction? 2) Consequently: How and when do they apply different (argumentative) modes of justification and/or other resources (or mechanisms) in defining what should count as ethically (un)acceptable research and clinical practice in ART? 3) And finally: What role do these scientific societies see for themselves when it comes to defining what counts as ethically (un)acceptable research and practice?

While the first two questions should have become clear through the detailed presentation of my research interest above and which will be dealt with centrally in Chapter 6, the third one aims at the more general question of self-regulation (or: governance in a broader sense) in this specific context, which can be mapped through the other two questions based on the chosen material of the ethical opinion papers. Building on this, the third question will then be the focus, especially in Chapter 7.

After having detailed all the methodological and practical aspects of my research as well as reminded the reader of my research questions, I now move on to the concrete comparative analysis of the cases by focusing on their distinct justification work.

Chapter 6: Bioethical decision-making and its modes of justification: Arguments and other procedural modes in the bioethics discourse of two ethics committees

The analysis of the various modes of justification used and performed by the two ethics committees being examined is at the center of Chapter 6. During the course of my analysis, I have primarily identified and made visible three argumentative modes of justification in the ethics committees' opinion papers. But I have also identified another mode of justification at a procedural level that I deem important in this context. As I have already stressed, the committees follow certain discursive rules in a Foucauldian sense. They use these rules to create a solid basis in order to legitimize their positions and decisions. Thus, we can identify certain *procedural modes of justification* and, on another level, we can find other *argumentative modes of justification*:

- *Rules of deliberation* and *composition of committee members* (as procedural modes of justification, ***Chapter 6.1***)
- *Scientific evidence* (as the prime argumentative mode of justification, ***Chapter 6.2***)
- *Biomedical principles* (as a common argumentative mode of justification in bioethical decision-making, ***Chapter 6.3.1***)
- The *informed consent*, based on the autonomy principle, and as such it can be seen as a specific twist of the principle-based argumentation (but which is dealt in this work as a further particular argumentative mode of justification, ***Chapter 6.3.2***).

The procedural mode involves the particular *composition of such a committee*, which means the diversity of the committee members and their selection, as well as the specifications of their *rules of deliberation* that they follow (e.g., consensus-based) to produce their ethical opinion documents. This mode refers to the very nature and conditions of the committee's negotiating space under which its ethical statements are produced within such a scientific society. I consider these procedural aspects of the committees in the first step in Chapter 6.1, before turning to focus on the 'outcomes' of these deliberations: *the ethical opinions*; these opinion papers are at the *core of my analytical interest* and which I scrutinize in Chapters 6.2 & 6.3.

I focus particularly on these ethical opinions in which argumentative modes of justification are enacted as a crucial form of legitimization. My research is guided by an analytical interest in how these ethics committees develop such argumentative modes of justification as they seek to define ethically acceptable practice (clinical as well as research). In doing so, they seek to legitimize their positions precisely in the form of these written ethical opinion papers. At the same time, I examine how specific kinds of moral truths are co-produced with these modes of justification. The constitutive perspective towards these documents also implies that it is not a matter of (e)valuating and judging these practices of producing and ethically shaping the discourse on reproductive technologies. Instead, it is, as we are used to doing in STS, a matter of questioning how people – in this case, the two ethics committees – justify these practices by providing (legitimate) argumentative responses to (sometimes controversial) medical practices

in the area of reproductive technologies. At a fundamental level, what I want to know is how they construct the very meaning of 'legitimate' medical and/or research practices and how they 'justify' their responses with and within such ethical opinion papers.

These argumentative modes of justification – scientific evidence, biomedical principles and the informed consent – relate in different ways to each other in both of the two cases. This means that each of the individual committees constructs and establishes particular hierarchies, priorities and relations between these justificatory modes, on which I aim to elaborate in detail in this chapter. This can be traced back to different factors in each case and becomes visible only through such a detailed and comparative approach.
Importantly, I should mention here that two of the justificatory arguments – informed consent and the biomedical principles – are two facets of the same order of justification. This is the reason why I detail them in the same chapter (6.3), but under separate sub-chapters (6.3.1 & 6.3.2), because they still form two distinct modes of justification. Whereas scientific evidence is a fundamentally different mode of argumentative justification, which becomes incrementally dominant in ethical evaluations. This is the reason that I put it center stage in my *justification analysis* (6.2). Moreover, scientific evidence carries the potential to act as a potent adjudicator in such ethical statements and to overperform in justifying acts and practices when it comes down to deciding statements.

I am convinced that these ethical opinion papers, and the modes of justification developed throughout, reveal and offer some crucial entry points in order to understand how these committees and organizations think and act in general, and what role they envision for themselves in matters of governance and self-regulation in their field, especially when it comes to reproductive technologies. Indeed, it turns out that these argumentative modes of justification function as particular kinds of discursive rules, which the committees follow and which permeate their ethical evaluations.

6.1 Procedural modes of justification: Rules of deliberation and the composition of ethics committee members

Before presenting the document analysis of the ethical opinions, I will first discuss the composition of the two committees and other aspects that can be seen as their deliberative rules, such as the conditions of document production they define under which guideline documents, position-, or consensus statements are produced. This can be understood as a procedural mode for justifying the kinds of ethical opinions they produce (and the positions therein), since they are formed under precisely these specific procedural conditions that are defined in advance as legitimate frameworks. In this way, through the establishment of rules about how to negotiate as well as maintaining a diverse and fairly elected membership (so whom to include as a relevant and knowledgeable party to discuss these ethical issues), the documents themselves acquire a basis of legitimacy. These procedural modes of justification define the space through which they also respond to issues of value pluralism (and to prevent

a respective potential relativism) in (bio)ethical decision-making. It is worth mentioning in this context that EHSRE is much more explicit when it comes to these procedural aspects of how their committee is composed and elected, whereas ASRM is far more precise about the conditions of document production. In a specific sense, this indicates that both of them put slightly different emphases on what they deem important (to be transparent about) when it comes to bioethical decision-making and its justification.

Composition of Ethics Committees – performing diversity: I have already described the two ethics committees in chapter 5; however, I will go into more detail here about the composition of the two committees and explain how this composition is achieved. Unlike the ASRM, ESHRE, for instance, provides detailed information on this procedural aspect in their so-called 'bylaws and governance terms' (which are accessible on the society's website). The *ethics committee of ESHRE* was founded in 1985 and is comprised mainly of ethicists, physicians, and natural scientists/researchers and also includes a patient representative and sociologists. For some of their earlier TF documents and their more recent ethics documents, they also invite external experts with special knowledge on a particular topic to participate in the discussion and/or drafting of a particular document, which they mention in their acknowledgements section at the end of each paper. ESHRE defines the ethics committee as a standing committee with an advisory role, i.e. their main aim is to develop the position of ESHRE and to advise the ESHRE Executive Committee on the issues that they considered. The profile of members and terms of office (their internal rules) are also defined in their bylaws to make these processes transparent. Here they also define the basic principles of such a committee, its purpose, tasks, mission statement of the committee, its relation to the Executive Committee as well as the "terms of office and profiles of members".
This, for instance, constitutes for the ethics committee the requirement of an interdisciplinary composition, which is broken down as follows:

> "4x Biomedical (2 clinicians + 2 basic scientists) with an interest in ethics
> 1x Paramedical
> 1x Patient representative
> 2x Ethicists with broad professional expertise in reproductive medicine
> 2x "ex officio" member of the ExCo [Executive Committee]
> + ad hoc experts"

Further information is provided with regard to terms of mandate:

> "1 Clinician (SIG)[58] 2 years (term of mandate)
> 1 Clinician with experience in bioethics Max of 3 terms of 2 years
> 1 Basic scientist (SIG) 2 years (term of mandate)
> 1 Basic scientist with experience in bioethics Max of 3 terms of 2 years
> 1 Nurse representative (PG Board) 2 years (term of mandate)
> 1 Patient representative (Fertility Europe) Max of 3 terms of 2 years
> 1 Ethicist SIG coordinator Ethics&Law 2 years (term of mandate)

[58] SIG is the abbreviation for special interest group.

> 1 Ethicist Max of 3 terms of 2 years
> 2 Members of ExCo Ex Officio; 2 years (term of mandate)
> … Ad Hoc members Experts in topic of interest".[59]

This serves as an illustration of how they try to perform a kind of diversity through committee membership; this should indeed convince the reader, or the website's visitor of how far they respect and uphold the principle of value pluralism through integrating these different kinds of expertise, values and experiences within such an ethics board. Furthermore, ESHRE's Ethics committee takes a deliberative approach and is oriented towards "(…) ethical principles and fundamental human rights such as equality, non-discrimination, right to private life and family building" (ESHRE, 2021).[60] Outcomes of the committee are reports to the ESHRE Executive Committee and the general declaimed mission of the ESHRE ethics committee is to: "(…) examine ethically relevant issues related to reproductive medicine and reproductive science with a (potential) impact on patients, professionals and society as a whole" (ESHRE, 2021).[61] And as part of a scientific society, it also discusses topics related to freedom of research, research integrity and responsible innovation.

ASRM had likewise already composed its own *ethics committee* by 1985, triggered "(…) in part by the regulatory vacuum, indeed a Catch-22 of a go-ahead decision from a lapsed ethics board" which was established by Jimmy Carter's Secretary of Health, Education, and Welfare (at a federal level) and which lapsed during Ronald Reagan's administration (Thompson, 2005: 227). In contrast with ESHRE, however, their election process to the ethics committee is not made transparent in the same way, but instead only the concrete composition of the members involved in the committee has been available on their website since 2021. As their aim and task, they declare:

> This committee considers and develops documents regarding ethical issues that are relevant and important to reproductive health and medicine, the community of patients and reproductive health professionals as a whole. Key work: Ethics opinion documents and consulting on derivative materials. (ASRM, 2023)[62]

The committee likewise comprises different experts, such as physicians, theologians, ethicists, lawyers, psychologists, and researchers (e.g. geneticists). Yet, in contrast to ESHRE, it is noticeable that there is a majority of medical doctors involved when studying the list of committee members on the website, but also when viewing the list of contributors at the end of their ethical opinions. However, it is not entirely clear in which exact rhythms (in terms of mandate) that they become (re)elected, etc. However, according to my research and when looking at these documents, it seems that there is indeed a core group of people involved in the production of these ethical opinion papers.

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[59] https://www.eshre.eu/Home/About-us/Bylaws-and-governance/Internal-rules/Committees (see p. 12-13/ accessed on 23rd January 2023).
[60] https://www.eshre.eu/Home/About-us/Bylaws-and-governance; https://www.eshre.eu/Home/Committees/Ethics-Committee (accessed on 31st May 2021).
[61] https://www.eshre.eu/Home/Committees/Ethics-Committee (accessed on 31st May 2021).
[62] https://www.asrm.org/about-us/asrm-board-of-directors/asrm-committees/ (accessed on 23rd January 2023).

In addition, members – or at least one member – of the executive committee participate in both ethics committees to ensure good communication between both groups,[63] as well as other scientists and experts needed for specific topics.
However, it can be noted that while they have similar compositions of their ethics committees (so they probably also follow similar rules of its composition), they differ in making these processes transparent and visible. Since my analytical focus is particularly on the ethics documents, I will now discuss their processes and conditions of the specific types of document production that ASRM in particular makes the subject of discussion and transparency.

The conditions of document production represent a further procedural aspect of their justificatory work. ASRM, for instance, has published on their website an own section entitled "ASRM Practice Document Type and Methodology", where they describe the differences between document types, which include: guidelines, committee opinions, and guidance documents. And they explain further how, and under which conditions, they develop these specific types of documents.[64] These different types of documents are closely related to different rules of deliberation; for the development of these documents they specify the following:

> ASRM guidelines follow a rigorous developmental process based on documented, verifiable systematic reviews of the scientific literature. Summary statements within the guidelines include evidence-based recommendations intended to optimize patient care and help guide medical practice in the field of reproductive medicine. (ASRM, 2021)[65]

Committee opinions and guidance documents, in contrast, are not based on a systematic review because not all issues are approachable through a systematic review (for instance, when scientific literature is not yet available). These three document types are produced by the ASRM practice- as well as the ethics committee. While *opinion papers* represent *expert consensus*, guidance documents summarize suggested best practices in the context of existing literature (ibid.):

> The Practice and Ethics committees typically develop and update committee opinions and guidance documents, but they also collaborate with affiliated societies, other societies, and ad hoc document-specific task forces. All ASRM documents – guidelines, committee opinion, and guidance documents – undergo member and Board review before publication. (ibid.)

It is also interesting to note that the ASRM documents are regularly reviewed (and possibly replaced) for relevance and timeliness, which I already have pointed out before:

> (…) at least every 5 years. At the time of review, the document can be affirmed as is, revised, or retired. Documents can be revised sooner than 5 years if meaningful new data emerge before a scheduled review.

[63] https://www.eshre.eu/Home/About-us/Bylaws-and-governance (accessed on 31st May 2021).
[64] https://www.asrm.org/news-and-publications/practice-committee-documents/additional-documents/asrm-practice-documents/ (accessed on 31st May 2021).
[65] https://www.asrm.org/news-and-publications/practice-committee-documents/additional-documents/asrm-practice-documents/ (accessed on 21st May 2021).

> Sometimes documents are retired because their content is substantially merged into a new or existing document. (ibid.)

These procedural modes of justification become increasingly relevant in both cases: for instance, in the case of ESHRE's TF transformation into an ethics committee (restructuring process), their 'ethics papers' become longer, more nuanced and diverse, in the sense of including a broader spectrum of aspects related to an issue and in terms of including an own section, in which they precisely describe their deliberation process, i.e., making their process of deliberation transparent (e.g. the process of consensus-making).[66] As an example, in a relatively recent paper entitled "The ethics of preconception expanded carrier screening in patients seeking assisted reproduction" (2021), they clarify the objectives of this paper, its process of development and its limitations:

> This Ethical document represents the views of ESHRE, which are the result of consensus between the relevant ESHRE stakeholders and, where relevant, based on the scientific evidence available at the time of preparation. The recommendations should be used for informational and educational purposes. They should not be interpreted as setting a standard of care or be deemed inclusive of all proper methods of care nor exclusive of other methods of care reasonably directed to obtaining the same results. They do not replace the need for application of clinical judgement to each individual presentation, nor variations based on locality and facility type. Furthermore, ESHREs recommendations do not constitute or imply the endorsement, recommendation, or favouring of any of the included technologies by ESHRE. (de Wert et al., 2021: 12)[67]

Within an 'acknowledgment'-section, they further recognize the input of external experts who participated in the stakeholder review process, which they make accessible via a link. Furthermore, they specify the different roles of the authors, in terms of who drafted the main argumentation of the paper, who provided methodological or other support, and who discussed and approved the final version of it. Then they include an own section on the funding, where they mention that the writing group did not receive payment for writing such a paper, but that ESHRE covers e.g. meeting-related costs; lastly, they have a section of potential conflict of interest issues, mainly referring to one person who works at a department that received grants from pharmaceutical companies (ibid.).[68]

By making all this information transparent, they once again perform that they are serious about the value of pluralism and the principle of deliberative democracy in bioethical decision-making and position development. In this context, the ASRM has also changed the wording of its 'Acknowledgements' section, which previously read as follows: „While this document reflects the views of members of that Committee, it is not intended to be the only approved standard

[66] Just recently, it was posted on the website that the ethics committee initiated to update all TF documents, see: https://www.eshre.eu/Specialty-groups/Special-Interest-Groups/Ethics-and-Law/Documents-of-the-Task-Force-Ethics-Law (accessed on 6th June 2023).

[67] https://academic.oup.com/hropen/article/2021/1/hoaa063/6134009#supplementary-data (accessed on 31st May 2021).

[68] https://academic.oup.com/hropen/article/2021/1/hoaa063/6134009#supplementary-data (accessed on 31st May 2021).

of practice or to dictate an exclusive course of treatment in all cases“ (ASRM, 2013: 1526).[69] And now reads:

> Although this document reflects appropriate management of a problem encountered in the practice of reproductive medicine, it is not intended to be the only approved standard of practice or to dictate an exclusive course of treatment. Other plans of management may be appropriate, taking into account the needs of the individual patient, available resources, and institutional or clinical practice limitations. (ASRM, 2021: 877)[70]

Even if it is a small change, it reveals a more nuanced way of acknowledging that, on the one hand, the situated factors that exist within a clinic, or doctor's practice or any other facility type, but it is also emphasizing, on the other, the necessity of creating a plan to manage the particular issue at hand. A prominent recommendation of ASRM is that clinics should draft such plans of management within a written policy. An interesting difference between the two arises in the way in which they express the same idea: while EHSRE speaks about patient care ('standard care'), ASRM speaks about 'appropriate management of a problem'. There are certain logics at play that become apparent through such formulations to which I will return more closely in chapter 7.

But even in these official records, consensus cannot always be reached. Hence, their deliberation might also result in an *expert dissent* (Bogner, 2015), which can be observed on an argumentative level as well, by looking at how they express different positions and possible dissent, and yet this is done within a *consensus approach*. For instance, when considering sex-selection for 'non-medical' reasons, ESHRE's committee has stated:

> This Task Force document revisits the debate about the ethics of sex selection for non-medical reasons in the light of relevant new technological developments. (…) While stressing the new urgency that these developments give to the debate, the Task Force did not come to a unanimous position with regard to the acceptability of sex selection for non-medical reasons in the context of assisted reproduction. Whereas some think maintaining the current ban is the best approach, others are in favour of allowing sex selection for non-medical reasons under conditions that take account of societal concerns about the possible impact of the practice. By presenting these positions, the document reflects the different views about this issue that also exist in the field. Specific recommendations include the need for a wider delineation of accepted 'medical reasons' (…). (ESHRE TF 20, 2013: 1)[71]

By presenting the different positions (basically two positions, including a pro and a con, or rather, a cautious position) as a reflection of the different views that exist in the field, they acknowledge and perform the legitimacy of occupying different positions (value pluralism) towards this issue. Also, the wording is interesting because they do not call it disagreement or something similar, but instead state that "the TF did not come to a unanimous position", which also represents a much more attenuated form of expressing dissent. It is exactly here where

[69] https://www.asrm.org/globalassets/asrm/asrm-content/news-and-publications/ethics-committee-opinions/access_to_fertility_treatment_by_gays_lesbians_and_unmarried_persons-pdfmembers.pdf (accessed on 31st May 2021).

[70] https://www.asrm.org/globalassets/asrm/asrm-content/news-and-publications/ethics-committee-opinions/access_to_care_for_transgender_persons.pdf (accessed on 31st May 2021).

[71] https://www.eshre.eu/Specialty-groups/Special-Interest-Groups/Ethics-and-Law/Documents-of-the-Task-Force-Ethics-Law (accessed on 1st June 2021).

we can observe the kind of justification that is being enacted through these procedural elements that become in this case discursively constituted. Through that, they also establish a connection between society, the professional membership and the organization. The ASRM, in contrast, expresses its position on the matter as follows:

> In conclusion, ART practitioners who currently offer or decline to offer sex selection for nonmedical purposes do so against a varied ethical and legal backdrop. Recognizing reasoned differences of opinion, the ASRM Ethics Committee has not reached consensus on whether it is ethical for providers to offer ART for sex selection for nonmedical purposes. Arguments regarding patient autonomy and reproductive liberty have been offered in support of the practice. Risks and burdens of the procedure, gender bias, sex stereotyping and nonacceptance of offspring, efforts to guard against coercion, and issues of justice all raise concerns about the practice. Practitioners must take care to ensure that parents are fully informed about the risks and burdens of the procedure and that they are not being coerced to undergo it. Because the practice is so controversial, clinics are encouraged to draft and make available written policies setting forth whether and under what circumstances nonmedical sex selection will be available. When nonmedical sex selection is offered in clinical practice, clinic employees with objection to the technique must be permitted to absent themselves from its provision. (ASRM, 2015: 1421)[72]

They speak about not 'reaching consensus' within the committee by listing some arguments for and against this practice and technology, framing their expert dissent rather in terms of a self-regulating medical community (i.e., actively emphasizing the role of informing the patients and with that leaving the decision-making authority with the practicing physicians and the individual clinical contexts). They only formulate some guidance regarding the conditions under which it might be practiced from their professional point of view. Therefore, one obvious difference refers to the scope of their statement. While ESHRE formulates its arguments rather in more general, technology-bound terms – the *ethical acceptability of nonmedical sex-selection in context of ART* – ASRM moves it into the clinical and provider context (autonomy) – *on whether it is ethical for providers to offer ART*. This highlights the dominance of patient and provider autonomy in the US context and the approach of implementing (operationalizing) these principles through the practice of informed consent, which is also articulated here as an argumentative solution.

ESHRE seemingly constitutes the issue at stake on the level of principle, at least in the way how they put it in their written document, whereas ASRM very much focuses on different practical contexts in which ART is practiced and if it might be ethical to offer under specific conditions. This does not mean that ASRM does not address the social issues associated with this practice, as one can obviously notice (for example, possible stereotyping, etc.), but that they rather see it as the practitioners' responsibility to do so (provider autonomy). It makes a difference to ask from a rather general (ergo societal) level if the use of such technologies is desirable in terms of a common benefit. I would refer to this kind of questioning as a more general and principled way of inquiry, or with the words of Boltanski and Thévenot one could say this orientation is underlain by a civic order of worth (oriented towards collective welfare). The ASRM's expert dissent, on the other hand, is much more pragmatically oriented, or at least formulated that

[72] https://www.asrm.org/globalassets/asrm/asrm-content/news-and-publications/ethics-committee-opinions/use_of_reproductive_technology_for_sex_selection_for_nonmedical_reasons-pdfmembers.pdf (accessed on 1st June 2021).

way: “Practitioners offering assisted reproductive services are under no ethical obligation to provide or refuse to provide nonmedically indicated methods of sex selection” (ibid.: 1418). This statement reflects in a way a robust form, or understanding of self-regulation in the US context. This is the reason why it is important to follow up on exactly these modes of justification that become articulated, and thus enacted, within such ethical opinion documents. To return briefly to how dissent is embedded in their consensus-building approach; another striking feature here is the way they describe it, namely ESHRE speaks of “the Task Force did not come to a unanimous position with regard to …”, while ASRM states: “the ASRM Ethics Committee has not reached consensus on …”. Consequently, *consensus-making* is a common approach in bioethical decision-making, as e.g. ASRM explains explicitly in their descriptions of how they develop different kinds of documents. This can be classified as a further justificatory moment because it rationalizes the methodology of document development. In this way, they make the process transparent, at least to a certain but important degree, which allows professionals, members and perhaps even other experts (such as policy makers) to use these documents in certain ways and in certain contexts. At the very least, it indicates some idea of how these documents might be used.
Simultaneously, it also signals that ASRM as a non-state actor (NSA) definitely has the power to perform such rules and set standards in the field of ART:

> In 2020 the WHO Executive Board renewed the ASRM’s status as a Non-State Actor (NSA) in official relations with the WHO. In this role, the ASRM is one of the few organizations worldwide assisting the WHO in achieving its global health objectives. (ASRM, 2021)[73]

As they further point out, they are truly proud of this status and the role they occupy in relation to the WHO, because they cross political boundaries in expanding global reproductive health. Or, as one of their previous presidents put it: “Patients the world over deserve access to the best care possible. In an increasingly interconnected world, this cannot happen by nations acting alone” (Catherine Racowsky, PhD, 2020 President of the ASRM). Or as the ASRM 2020 CEO Ricardo Azziz, MD added in 2020:

> We are pleased to renew our status as an official NSA with the WHO. That is but one part of our global presence, however. We have members in over 100 countries, conduct programs with our counterparts all over the world and have initiated projects in multiple countries. ASRM’s role as a leader in the global reproductive health community is something we take quite seriously, and we look forward to continued collaboration with our world-wide partners. (ASRM, 2021)[74]

Thus, consensus-building as a deliberative approach can obviously lead to dissent. From a perspective of justification, however, it is important to consider how this dissent is generated and the fact that it takes place within this particular deliberative framework. In any case, expert dissent here entails that the concern either remains open for negotiation (as in the case of ESHRE), or that the decision-making authority has been shifted into individual clinical contexts

[73] https://www.asrm.org/about-us/initiatives/asrm-achieves-ngo-status-with-world-health-organization/ (accessed on 1st June 2021).
[74] Ibid.

and is the providers' responsibility (as in the case of ASRM) depending on different conditions they determine (resources, skills, preparedness, facility type). In the latter case, they usually define the conditions under which the practice might be implemented into a clinic or doctor's practice. This means, in the first case, they call for constant negotiations in light of further advancements and generated knowledge, while in the second case, decision-making authority tends to be located into the realm of practitioners practice (self-regulatory moment).
The paradox, however, remains that the technology (or its new and expanded usage) has to be practiced in one way or another to generate exactly this kind of practical knowledge. It may also occur that they propose a particular setting in which to create such a knowledge basis. For instance, ESHRE has advocated by referring to the British Human Fertilisation & Embryology Authority (HFEA), which can be seen as a common reference point for professionals in this field of reproductive medicine:

> A possible approach has been suggested by the Human Fertilisation & Embryology Authority in its 2003 report on options for regulating sex selection: allowing (preconception) sex selection in a trial setting involving proper pretreatment implications counselling and serious monitoring of all relevant aspects. Such a trial 'would permit an assessment to be made of the extent and profile of demand for this service, and controlled follow-up of families involved, including the effects of selection on the subsequent treatment and long-term psychological development of the children' (HFEA, 2003). As a matter of caution, it would be advisable to use 'family balancing' as a condition for access to this trial, with the aim of neutralizing the most important potential dangers and disadvantages of unrestricted sex selection (Pennings, 1996). (ESHRE TF, 2013: 6)

This is indeed an interesting recommendation for the introduction of a new technology or a controversially perceived medical intervention into practice – a kind of real experiment, but under well-defined and monitored conditions. Overall, in both cases, we can see a tendency not to deny a technology or a new procedure per se unless there would be evidence that a technology or procedure is definitely too risky at the moment. This clearly has to do with the fact that both of them belong to a scientific society that is, of course, particularly committed to the science and advancement of (assisted) reproductive medicine and biology. Taking all these aspects together, whether or not an application is too risky, or other related aspects that might make an application unsafe at a present stage, depend precisely on how boundaries and limits are defined within such bioethical negotiation spaces (ethical opinions, and other formats or outcomes of deliberation).
Hence, these ethical deliberations can indeed be seen as something in-between, functioning as a crucial *intermediary step to scientize an issue* by clarifying, defining, shaping and bringing various values (positions) and facts (scientific evidence) at the table that are involved in research and clinical practice in this area. In other words, consensus-building also refers to the value sphere in which the foundation is laid for addressing and making an issue accessible to be addressed as an epistemic question (Bogner, 2021). The way facts (in the form of scientific evidence) and values merge seamlessly together in the field of bioethics is a particular interesting aspect; whereby scientific evidence operates as a supposedly 'objective' vehicle in bioethical decision-making, seemingly separating facts from values.

Thus, it is important to scrutinize the different modes of justification that both committees systematically introduce, work through, and combine in particular ways to develop and justify their positions. By defining the conditions under which different medical practices, procedures and technologies should and can be justified as (un)ethical at a particular point in time, they enact the very issues at stake and by that indeed perform a specific kind of governance.
Henceforth, I will focus on the three other argumentative modes of justification (i.e. legitimizing arguments), including scientific evidence, and subsequently the informed consent and principle-based arguments and how those get realized, re-articulated and related in their documents.

6.2 'Empirical evidence' as truth regime: A dominant argumentative mode of justification in (bio)ethical decision-making

> An ideological position can never be really successful until it is naturalized, and it cannot be naturalized while it is still thought of as a value rather than a fact. Accordingly, neoliberalism has sought to eliminate the very category of value in the ethical sense. Over the past thirty years, capitalist realism has successfully installed a 'business ontology' in which it is simply obvious that everything in society, including healthcare and education, should run as a business (….). 'The reality principle', Zupancic writes, is not some kind of natural way associated with how things are ... The reality principle itself is ideologically mediated; one could even claim that it constitutes the highest form of ideology, the ideology that presents itself as empirical fact (or biological, economic…) necessity (and that we tend to perceive as non-ideological). It is precisely here that we should be most alert to the functioning of ideology. (Fisher, 2009: 17)

One might wonder why and how a value question comes into being and how it actually becomes transformed into an epistemic (ergo technical) question that can supposedly be judged and decided on the basis of available scientific evidence. The question that results from this might be: what is or becomes defined as evidence (as 'objective' evidence) and hence, what is defined as legitimate evidence to actually justify an ethical position (that is no longer perceived as a value issue) towards (a potentially controversial) medical practice?
In this regard, Fisher's diagnosis in the quote above is worth bearing in mind when we look at how ethical questions are constantly tied to questions of evidence in these ethical opinion statements. Fisher was not so much concerned with how a value question is transformed into an epistemic or technical question, but instead went one step further and directed the focus on how it actually becomes an empirical fact or is perceived as an economic, biological necessity (i.e. that it is no longer, even in the slightest, perceived or recognized as a value issue or question). This then leads to a completely different situation because it is negotiated on a different basis (namely, within a new 'truth regime' – as Foucault would have called it – as if there would be the possibility to base any kind of decision, be it medical or political, on a neutral basis).
Or as Kirsten Bell (2017) already rightly pointed out, health constitutes a kind of trump or meta-value, sometimes operating to disguise what is a fundamentally political, moral and economic (for instance, when counselling how people should think and live). As she also rightly brought up, to speak of health has always been to speak about morality, but here Fisher's notion of 'ideology' (as 'naturalization') becomes particularly illuminating in the context of *evidence-based medicine* and its constituents of epidemiology and ethics that made it possible to emerge

as a kind of magnet pull that draws also phenomena initially outside their orbit eventually into it (Bell, 2017). Or, as Tamar Sharon has pointed out, the potential dangers that health as a higher common principle – what she calls a vitalist order of worth – can also entail:

> Ubiquitous, constant health (self-)monitoring via mobile apps, virtual medical assistants and health maps, for example, may well lead to more preventive and personalized medicine and better health outcomes (...) But it also curtails individual autonomy and privacy. The prominence of the vitalist order may also legitimize the presence of data corporations and their contributions to healthcare and medical research while downplaying the various costs of this involvement—in terms of the market price the public sector may need to pay for the treatments and services that these corporations will develop, or in terms of a loss of democratic control over health data as a public resource. (Sharon, 2021: 323)

Of course, when something is performed and argued in the name of medicine and health (operating nowadays as meta-value or even as an empirical fact), and is, in addition, based on the so-called 'best available' evidence it is difficult to resist (through that, it becomes ethically robust and justifiably defined and fixed).

Value questions and knowledge production are longstanding matters of concern in the field of STS and have been studied in different contexts and forms. However, my point of departure here is not so much to uncover the logic of evidence-based ethics as such (which has been Bell's undertaking), but rather its functioning as justificatory, thus potent decision-making tool (and in this sense as a potent truth regime). I do this by analyzing in detail how the two ethics committees justify new technologies and related medical practices as ethically acceptable by invoking evidence as a potent adjudicating device. In a specific sense, ideas of ethics, moral truths, and knowledge about reproductive medicine and its technologies are co-constructed in these ethics papers, similar to what Jasanoff demonstrated in context of legal proceedings in the US in her book "Science at Bar" (1995), where she discussed the interactions between science, technology and law in the US courtrooms, and how they co-produce knowledge together in these arenas and even their associated capacity for co-producing ideas of truth and ideas of justice (Jasanoff, 1995).

Evidence-based ethics must be seen in the context of this broader so-called paradigm shift: Evidence-based medicine (EBM) that emerged around the 1990s. The underlying claim is that the presence of reliable evidence, especially numerical evidence (as proofs), ensures better biomedical decisions, as if evidence would lead automatically and directly to better decisions. Empirical evidence does not necessarily mean the evidence per se, i.e. the results of research, but rather the strength of this evidence as probative force (proofs in terms of their significance). For example, there are existing different categories of evidences, one could speak of "weak evidence" or "high evidence" for a certain assumption or treatment method (I will come back to this point later on).

There are also some professional criticisms towards EBM, as for instance: unpublished material is not taken into account (e.g. discontinued studies, partial studies); results are dependent on the feasibility of a study; the applicability of the results to the individual patient is not always given; time scarcity of practitioners to engage with all scientific literature, especially in light of quickly renewed or updated knowledge; access to sources (open access) for traceability and

verification is only partially guaranteed; and clinical applicability may not be possible with certain concomitant diseases and some others.[75] However, in view of the time scarcity of practitioners and the excessive demands of regularly evaluating scientific literature on current studies themselves, professional societies have evolved that made it their task to produce high-quality systematic reviews and meta-analyses[76], so also these two organizations of this study.
ESHRE and ASRM also see it as their primary aim to perform these tasks in the area of reproductive medicine and biology. As already mentioned above, ASRM's guidelines are based on systematic reviews, which then include evidence-based recommendations. But as they indicate, committee opinions and guidance documents are not based on systematic reviews, because:

> Not all topics are appropriate for a systematic review. In some cases, the literature is not yet available. Committee opinions represent expert consensus, while guidance documents summarize suggested best practice in the context of available literature. (ASRM Website, 2023)[77]

Of course, this does not mean that evidence does not play a role here, but it is all the more interesting to study how they operate in these papers with evidence as a decision-making figure and justification. However, it must be noted that during the process of medical decision-making "(…) a broad spectrum of knowledge (or multiple dimensions of evidence), including scientific evidence, personal experience, personal values, economic and political considerations and interests, and philosophical principles" (Goldenberg, 2005: 5) are at stake, which complicates the whole matter and makes clear that all those dimensions have to be considered in the decision-making process, at least in one way or another. Thus, it never can be fully free of value judgements and actually the question arises of why it should be free from values: why are those so unpopular in (medical) decision-making, when „normative content seems to enter at all levels of decision-making, even in the production and presentation of the scientific evidence that is supposed to univocally inform evidence-based decisions" (ibid.: 5).
Because bioethics has a normative mandate built into its project from the very beginning, it is crucial to ask what that means in the context of an increasing movement of evidence-based ethics. This very much relates, and is similar, to what Bogner has called the "epistemologization of politics"[78] (Bogner, 2021) which describes some of the profound shifts in policy-making. He is very much concerned with the consideration of how value questions are transformed into knowledge questions in this area:

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[75] See: https://flexikon.doccheck.com/de/Evidenzbasierte_Medizin (accessed on 25th January 2023).
[76] For instance, one of the most well-known organization worldwide that is exclusively dedicated to creating and disseminating this kind of evidence and information is the Cochrane collaboration See: https://www.cochrane.org; https://www.cochrane.org/about-us (accessed on 25th January 2023).
[77] See: https://www.asrm.org/news-and-publications/practice-committee-documents/additional-documents/asrm-practice-documents/ (accessed on 25th January 2023). Or e.g. with regard to a current meta-analysis that is summarized by ESHRE regarding Covid-19 during pregnancy: https://www.focusonreproduction.eu/article/News-in-Reproduction-COVID-pregnancy-health-risks (accessed on 25th January 2023).
[78] Original title (German): „Die Epistemisierung des Politischen. Wie die Macht des Wissens die Demokratie gefährdet" (2021).

> The handling of political questions by expert committees can only function smoothly if the experts can rely on a general value consensus regarding a particular question. Only this value consensus does not make the (inevitable) value-laden nature of knowledge questions visible. We can only believe that there is such a thing as questions of pure knowledge that can be safely delegated if there is a broad consensus on values. (Bogner, 2021: 50; translated by the author)[79]

Health relies exactly on such a broad value 'consensus', i.e. as something that always, at any time and in any place claims a kind of universal validity, almost functioning as an empirical fact (or naturalization) in Fisher's sense. EBM has played an integral part in the formation of bioethics and its relationship is one of mutual elaboration, as Bell has shown convincingly in her analysis. As well as Bell, I am interested in the contemporary *concept of health* that is primarily characterized by its intimate intersection "(…) with several other equally unassailable values: namely, evidence and ethics (…)" (Bell, 2017: 3). The concept of *evidence* suggests a supposedly simple solution or answer to multiple and complex questions in biomedicine. Equally in bioethics, its particular handling might involve a potential fallacious belief that there is a direct and automatic way from evidence to the right (ethical/political) decisions (Bogner, 2021). Consequently, I ponder on how evidence is used by both ethics committees to justify, ergo legitimate, ethical decisions and to construct the very issues at stake in the area of reproductive medicine.

Scientific evidence is frequently used in all of their ethical opinion papers, although to a varying degree depending on the topic and the topic's historical drivers, such as a general movement of 'evidence-based ethics' that had already become prominent around the 1990s and strengthened since then on the agendas of health policy and research (Borry, Schotsmans, & Dierickx, 2005). Regarding this all-encompassing trend, Goldenberg emphasized:

> The technique of "evidence-based decision-making" offers what seems like a solution to this so-called "postmodern" problem, as it proposes to ground decisions in something concrete and universal, namely the evidence. (…) The rapid ascendancy of the evidence-based movement, which started in medicine and quickly spread to other professional disciplines, speaks to the movement's enormous appeal. Even the popularity of the *CSI* television series – which depicts "evidence-based" police work *par excellence* – demonstrates how the stability, fairness, and truth of "the evidence" have captured our imagination. (Goldenberg, 2005: 3)

Also, the EHSRE TF is making use of a so-called evidence-based approach towards ethical decision-making in assisted reproductive medicine. This evidence-base becomes consistently presented in a section labelled as: **'Background and Facts'**, which is interesting in itself. The structure of their ethics papers (Task Force documents in case of EHSRE) already reveals how the committee (and the organization) thinks in general. They usually structure their papers using the following three (or four) sections:

- A *'Background and Facts'* section,

[79] Original Quote in German: „Die Abwicklung politischer Fragen durch Expertengremien kann also nur dann reibungslos funktionieren, wenn sich die Experten in der betreffenden Frage auf einen allgemeinen Wertekonsens verlassen können. Denn nur dieser Wertekonsens lässt die (unumgängliche) Wertebeladenheit von Wissensfragen nicht sichtbar werden. Nur unter der Bedingung von weitreichendem Wertekonsens können wir glauben, dass es so etwas wie reine Wissensfragen gibt, die sich gefahrlos delegieren lassen" (Bogner 2021: 50).

- A section called: *'General ethical principles'*, and
- A section with: *'Specific considerations'*
- (sometimes) a fourth section with a 'conclusion' and/or '*recommendations*' part[80]

This is a noteworthy instance of boundary work through which they create the impression of being able to distinguish the ethical issues from that what is already (perceived) as stable, known and undisputed in a way, and which does not, perhaps, require further justification, or is simply justified by the invoked evidence.
In the case of ASRM's ethics committee, it is not equally obvious from the mere paper structure which role evidence plays in their ethical consideration because they do not follow a fixed structure in their ethical opinion papers. Instead, they seemingly follow a rather pragmatic approach, as one can see in their paper called "Moving innovation to practice: a committee opinion" (2015). However, in this paper, they guide the reader along using the following practical questions that they deem relevant to practitioners (referred to by ASRM as "providers") to consider:

- "Is there adequate evidence to support the effectiveness of the new intervention",
- "What are my motivations in adopting the new intervention in my clinical practice?",
- "Are the research findings applicable to my practice environment, and can I offer the new intervention effectively?", and finally
- "How do I talk to my patients about this new intervention" (ASRM, 2015: 1-3).

Although they do not have a strict scheme, they likewise start by assessing the issue with the available evidence, then proceed in a second step with examining motivations and then again, in a third step, consider how research findings (evidence and knowledge) are applicable in the respective practice context; the last question refers to another quite prominent mode of justification, especially in case of the ASRM ethics committee (though it is a ubiquitous legal protection of the autonomy principle in healthcare quite in general): *the informed consent (IC) procedure.* As we can see, ASRM usually starts similarly to ESHRE by introducing an issue with available evidence and its legal constituents: "The introduction of new strategies, tests and procedures into clinical practice raises challenging ethical issues involving evaluation of evidence, balancing benefits and harms, supporting patient autonomy, avoiding conflict of interest, and promoting advances in health care" (ASRM, 2015: 1). Thus, the evaluation of evidence and scientific evidence production becomes an ethical business, as Pickersgill has noted: "(…) science today is an 'ethical' business. The ways in which formal and informal ethical discourses and practices – what might be called 'regimes of normativity' – structure scientific work and the meanings it is ascribed with have, however, been unexplored" (Pickersgill, 2012: 579).

[80] See for instance in one of their papers, such as: "ESHRE Task Force for ethics and Law 20: sex selection for non-medical reasons" (2013).

Once more, when thinking with Fisher, neoliberalism (as an encompassing capitalist environment) has sought to obliterate the very category of value in the ethical sense by having "installed a 'business ontology' in which it is simply obvious that everything in society, including healthcare and education, should run as a business" (Fisher, 2009: 17). In this very sense, it comes not as a surprise that the evaluation and production of evidence becomes the primary ethical question and approach (and, in fact, the primary *business*) these committees have to deal with.

Empirical evidence seems to be this objective or universal device to solve this "postmodern" problem of value pluralism and its flipside of relativism, which might function as a supposedly neutral adjudicator in the case of ethical decision-making. Maya Goldenberg, for instance formulated it in this way:

> The techniques invoked in the name of "evidence-based" decision-making require a positivistic reliance on "the evidence" in its epistemological promise to ascertain truth or certainty by examination of the evidence. These techniques act to obscure the multiple and complex considerations that unavoidably go into health care decisions at both the micro- and macro- level and allows for the promotion of particular political agendas and interests under the guise of "better science". (Goldenberg, 2005: 6)

Thus, evidence-based decision-making is a normative concept too, as the very notion of evidence and what counts as evidence – so the constant moving and defining of its boundaries, what counts as reliable and valid evidence – is a social construct because it results always from a socially produced question (ibid.: 5).
Yet, there is a particular notion of evidence operating within the EBM movement, which Kirsten Bell has directed our attention to. Usually, evidence has to be evidence of or for something, therefore, it is different from 'data'. However, within EBM, this difference becomes obliterated, so that evidence seems to be almost the natural output of data and the methods used to obtain them hold much more weight (Bell, 2017: 84). Just to provide an illustrative example from the ASRM Ethics Committee:

> One needs to be confident of the data supporting the efficacy and safety of the new intervention before adopting it for use with patients. Was it developed and studied through adequately designed, powered, and performed research? Were appropriate subject protections provided? Were the data analyzed appropriately? It is important that the study design, data analysis, and conclusion should undergo peer review before adoption into practice. (ASRM, 2015: 2)

In this regard, Timmermans and Berg likewise note, regarding the process of standardization, that "(…) standards and guidelines can be discussed with regard to their scientific qualities or their technical adequacy, but to speak of their political nature seems almost to commit a category mistake" (Timmermans & Berg, 2010: 18).
Hence, scientific evidence in biomedicine becomes a powerful decision-making tool and thus a kind of truth regime from which, due to its supposedly objective character, the right decisions arise quite naturally and as if by themselves. For this reason, I would now like to reflect further on the particular role and use of empirical evidence as a justificatory device in these specific ethical statements of the two ethics committees.

6.2.1 The role of 'empirical evidence' as a justificatory device in (bio)ethical opinion papers of ESHRE & ASRM

One prevalent use of empirical evidence as a justification is negative evidence (evidence of harm). In the case of ESHRE, this use comes particularly in form of the following phrases: *'there is no evidence for indicating harm'*, or *'there is no evidence available, thus …',* which means either the technology cannot be banned, or it should not be used temporarily yet. These kinds of arguments consist of deciding statements grounded in either a lack of data, or a kind of negative evidence of harm, both of which can imply either an objection or an acceptance of a procedure or technology, whereby the latter is the more frequent case.
In contrast, ASRM uses evidence rather as a kind of positive proof of something (that is, more as a positive argument for the use of a procedure or technology). While this type of negative evidence is used differently in the ethics papers of ESHRE, it always functions as a kind of adjudicator when it comes to temporal position claims: once as temporary suspension (a moratorium), or as an argument in favor of applying a particular technology, because paradoxically limited data (which is almost synonymous with evidence and thus understood as a lack of evidence base) might not function as a legitimate ground for rejecting the application of a technology (i.e. when no harmful effects are verifiable). For example, the ESHRE TF has made a strong connection between the need for objective evidence and the avoidance of prejudice and discrimination in the context of IVF:

> To avoid prejudice, arbitrariness and discrimination, objective evidence must be sought to be able to offer good reasons for refusing assistance. This requirement does not only apply to IVF but to all medical interventions enabling procreation (including e.g. microsurgical interventions for fertilization after sterilization and hormonal stimulation). (ESHRE TF 13, 2007: 2585)

Against this backdrop, some of the justifications that get mobilized through the use of negative evidence become clearer. The following *four selected quotes* should serve to illustrate these justificatory arguments. The first quote:

> (1) Similar concerns have been raised for many new applications in the field of assisted reproduction. Without empirical evidence about serious harmful effects, this cannot be considered as a sufficient reason to reject the application. (ESHRE TF 11, 2006: 3051)

This statement is concerned with posthumous reproduction being quite a rare practice as the ESHRE TF is stating, but one which obviously is being requested by patients, otherwise they would not consider the ethics of this practice. They conclude that a *lack of empirical evidence cannot function as a legitimate argument for rejecting this application*, which implies that it has to be practiced in order for further empirical data to be collected on this practice (i.e. follow-ups on the consequences). Consequently, this way of using negative evidence (of the lack thereof) means there is 'no objection' to the application of the technology in this way. This is an illustrative instance where the factual and the moral get conflated into negative evidence of harm, which is a coproduction of morality and non-knowledge in a way.

In this regard, Erik Aarden has called attention to the intertwinements and co-productive dynamics of knowledge production and politics in public health research in India (Aarden, 2019). In his investigation on the ambivalences of producing evidence on mortality statistics in India, he has shown the politics behind its production. As he pointed out throughout his study, quantification is powerful because numbers are supposed to correspond to a known and measurable reality, which means that anything that can be expressed in numbers must also be politically relevant and consequential. Thus, statistics as a main descriptor of a given society and that society itself are thus mutually constitute each other (Espeland & Stevens, 2008), which reflects and intersects with particular dynamics and ideas of relevance, expertise and power. Therefore, it is important to keep this in mind:

> (…) a pluralistic democracy that is capable of considering the social meaning and limitations of quantitative evidence is more vital than ever. Numbers form only a part of the picture, so, recognising the plurality of knowledge forms that matter to health in people's everyday lives is key to pursuing comprehensive improvements in public health. (Aarden, 2019: 47)

This also shows quite revealingly, as Goldenberg has rightly noted, how: "(…) the stability, fairness, and truth of 'the evidence' have captured our imagination" (Goldenberg, 2005: 3), namely also beyond the medical field.
In this context, I will give a second statement made by ESHRE on the use of negative evidence:

> (2) We are aware of particular concerns when the gestating woman also provides the oocyte (partial surrogacy). Until we have further evidence, we would discourage this kind of surrogacy agreement. (ESHRE TF 10, 2005: 2706)

This example, in contrast to the first, presents a different use or result of the 'no evidence argument'. It is concerned with a particular surrogacy arrangement and leads to a temporary halt of this particular practice. They express the fear that partial surrogacy could indeed lead to a much more complicated relationship between a third party (surrogate with her own oocytes: genetic and gestating mother) and the intended parents. This arrangement, by the way, could present a legal problem in most other countries as well. This is an instance, where the ESHRE TF is calling for more evidence and research, otherwise it cannot be legitimately practiced. Interestingly, however, is the fact that the same kind of argument (a lack of evidence) which leads to the justified conclusion in one case that a lack of evidence does not constitute a sufficient basis for rejecting the application, whereas in the other case, it leads exactly to the inverse decision. Although both of the applications could be seen as rather controversial practices, it is the second case (the surrogacy arrangement) that causes continued hesitancy even more so in respect of legal considerations. This constitutes again a profound instance where the factual and the moral get conflated into this particular type of negative evidence of harm. In this case, however, it is not so much the evidence that causes hesitation, but indeed the social and legal reservations about this delicate practice.
This *third* justificatory argument is concerned with the cryopreservation of reproductive material, a long-standing issue of bioethical reflection and assessment because it can certainly be seen as a major advancement in the field:

(3) There is no evidence that cryopreservation of sperm or embryos has a deleterious effect on the offspring. As far as oocytes and ovarian tissue are concerned, the number of children born is too small to know with certainty. There are, however, theoretical risks that need to be followed up. (ESHRE TF 11, 2006: 3050)

Here they are stating that, so far, no deleterious effects have been identified with this practice, however, there might be theoretical risks (whatever that means precisely) involved that have to be followed-up on as the application of this technology progresses. This justification fits with the first one discussed in this selection where little evidence (which means little data) does not imply an objection to the practice, but results in a call for more follow-up research (which means more long-term studies), a further nuanced layer that gets introduced here.
The *last quote* in this demonstration of the specific use of 'no evidence' considers complex ethical questions involved in the application of preimplantation genetic diagnosis (PGD) for human leukocyte antigen typing of embryos (i.e. with the creation of a second child that should be a donor to a first, sick child):

(4) In order to collect reliable information on the fate of the children and the families that apply this technology, careful follow-up should be performed. Present concerns about the psychological and social consequences for the donor sibling can only be corroborated or refuted by empirical research. It is therefore advisable to collate a register of such donations for this purpose. (ESHRE TF 9, 2005: 847)

This is an issue that the ESHRE TF for ethics and law already touched upon in a previous document on PGD, although some members of the TF thought it deserved a further and more detailed analysis because it is a quite complicated matter. It includes the consideration of various dimensions: the motivations of the parents, the different types of donations that would be given by the donor child. Such types include transplantation of haematopoietic stem cells (i.e. cord blood or bone marrow), which is ethically justifiable under particular conditions, or deemed morally unacceptable in case of the donation of non-regenerative organs because of the "more than minimal risk of the donor" (ESHRE TF 9, 2005: 847) and the general position that organ donation in case of children or incompetent adults is not considered a morally acceptable practice. They suggest that in such cases, parental motives are always of utmost relevance for the moral evaluation, especially regarding the upbringing of the future child and thus, psychological counselling before treatment is highly recommended.
This also implies that it has to be evaluated individually on a case-by-case basis, but here again (and differently from the previous example) what little evidence there is suggests staying cautious and functions as a basis to argue for more research: "It is concluded that, if parents intend to love the child, the creation and use as a donor is not inherently disrespectful" (ibid.). The deciding factor, in this case, depends not so much on scientific evidence solely but instead is closely associated with the motives of the parents, which indicates that such delicate decisions cannot be based exclusively on 'technical' knowledge, so to speak.
However, evidence operates as an argumentative precondition and, as such, it is indeed a powerful justificatory move: "Present concerns about the psychological and social consequences for the donor sibling can only be corroborated or refuted by empirical research" (ibid.). In terms of self-regulation, evidence very much constitutes a knowledge device with

which decision-making power is tried to keep within the rows of the profession, it is, so to speak, the primary resource (i.e. the argument of the profession) which explains why it becomes such an authoritative instance in bioethical decision-making and EBM in general.
With this in mind, one can conclude that missing evidence or a lack of data (which is almost synonymous in these accounts) does not necessarily lead to a rejection of a technology, but rather the opposite and that, in most cases, it cannot function as a legitimate basis for refusing an application. This way of reasoning is sometimes also underpinned by arguments about the importance of technological advancement for patients because those advancements might enable them to get 'healthy' children. When it comes to particular third-party reproductive constellations or other reasons than infertility in a strict sense for requesting ART (as the case with HLA-matched child for a sick sibling), it seems to be much more difficult to justify this practice using a lack of evidence. Either way, negative evidence – whether as an argument for or against a new intervention – means that the intervention needs to be practiced to gather empirical data, and that means, in one way or another, more work for these scientific societies and science in general.
In case of ASRM, in contrast, this very specific use of negative evidence as a justificatory argument is not as common as it is in the case of ESHRE, unless that negative evidence concerns emerging technologies that seem to be gaining prominence in the field. The use of positive evidence, i.e., 'evidence for something', is a similar type of argument that gets more often used by ASRM. For instance, in their paper titled *"Moving innovation to practice: a committee opinion",* they state:

> Clinicians considering the adoption of a new test, treatment strategy, or procedure should carefully consider the evidence for and against use of the new intervention, their motivations behind adopting the new intervention, the applicability of research findings to their clinical setting, their ability to effectively implement the new intervention, and their process for obtaining informed consent from patients. (ASRM, 2015: 2)

Here we can recognize a prioritization with regard to what counts most in assessing the ethicality of introducing a new intervention into a clinical practice context. At first, they nominate the consideration of evidence for and against a new intervention, then the motivations and benefits in adopting it, and finally introduce the applicability of research findings into a particular practice context, the ability to effectively implement it, as well as the process for obtaining informed consent. One can quickly realize that all these aspects are inspired by a strong commitment towards the EBM paradigm: everything that they list has to be informed by evidence but without explaining or defining exactly what that actually means, or what kind of evidence is meant.
What is clear is that, most of the time, evidence is equated with some sort of empirical data or research studies. As Kirsten Bell has pointed out with regard to cancer screening tests (for breast, ovarian and prostate cancer), "(…) the notion of 'informed choice' mediates the gap between the population-level EBM assessments of effectiveness and the individual patient" (Bell, 2017: 153). For instance, in another paper on cryopreservation, the ASRM ethics committee discusses the incompleteness of long-term data on frozen oocytes but relies on short-term data to argue for the practice. Remarkable is the temporality dimension that is

repeatedly brought into play when talking about a so-called transition period (which covers a time horizon of several years) in which treatments are justified with short-term data, while arguing for long-term data that has yet been collected through the steady application of the intervention:

> Data on the long-term safety and efficacy of planned OC are incomplete, partly because vitrification was adopted only in the last dozen years and partly because it takes time for significant numbers of women to return to use their cryopreserved oocytes and for their offspring to grow up. In this interim period, however, the ability to obtain viable embryos is proven. Embryos from previously vitrified oocytes show rates of fertilization, implantation, and clinical pregnancy that are comparable to those for embryos from fresh oocytes, although there can be variation among clinics (35–37). While only short term, birth reports indicate no increase in congenital abnormalities in infants from cryopreserved oocytes compared with other IVF infants (35, 38, 39). (ASRM, 2018: 1024)

In this quote (and also in the following quote), they define and thus justify the use of oocyte cryopreservation apart from medical reasons, such as gonadotoxic therapies. Planned OC is their specific terminology, which is chosen to avoid the dichotomous distinction between medical vs. non-medical reasons as is made, for example, by EHSRE's TF. However, I will return to these different terminological subtleties introduced by both committees throughout Chapter 7, which is about issue-making in the context of broader healthcare logics. The following quote illustrates how an innovation moves into practice, and at the same time it reveals the hierarchy of "ethical issues" that they believe must be considered when evaluating this new intervention and its various applications:

> While the ASRM Practice Committee and Ethics Committee approved the use of OC for patients facing therapies likely to be gonadotoxic (1–3), the Practice Committee declined at that time to recommend OC ''for the sole purpose of circumventing reproductive aging in healthy women,'' on the grounds that there were insufficient data on the ''safety, efficacy, ethics, emotional risks, and cost effectiveness'' for that indication (1). Since that time, further research on efficacy has been reassuring (4, 5). Increasing numbers of women are seeking planned OC and increasing numbers of physicians are providing it (6–8). In 2014, ASRM published a fact sheet on its patient education website, describing how women may use OC even if they are not facing a fertility-threatening disease (9). **All these factors point to planned OC as a medical innovation that is moving into practice**. As such, it raises ''ethical issues involving evaluation of evidence, balancing benefits and harms, supporting patient autonomy, avoiding conflict of interest, and promoting advances in health care. (ASRM, 2018: 1023; emphasis added)

Interestingly, in this section, they explain how this technology moves into practice, namely through demand and supply that becomes also a form of justification here. However, (a lack of) data and (the evaluation of) evidence are again mentioned as the first and major justifying factors, aside from the increasing demand by women and providing physicians, which leads an innovation to become an established medical practice. On the one hand, this shows how this question is framed in technical terms (at least retrospectively). On the other hand, it demonstrates quite well that an innovation does not move straight forwardly and perfectly well (i.e. evidence-based) into practice, but rather that it has to be practiced in one way or another to gather some sort of data, and specifically long-term data, so it has to be collected in a temporal sequence.

This speaks to the "unruly" nature of technology, as Mol called it, or the technological agency itself. As Mol and later Bell have succinctly pointed out, "Technologies do more than is expected

of them. What is more: they also change expectations" (Mol, 2008: 61) and they are far more fluid than a logic of choice would assume, as Bell rightly emphasized (Bell, 2017). Furthermore, in case of ASRM, it becomes visible that they have a clear imagination of how to distribute responsibilities, duties and rights, and who should be made responsible for what and in which respect. They obviously see themselves in the role of reviewing, collating, assessing and judging available evidence at a more general level. This should then serve as the basis for clinics and practitioners (or, to use their language, 'providers') to consider the evidence-base if they deem it responsible and justifiable to provide a particular technology to their patients, or not. This is a moment of the self-regulating capacity that ASRM is occupying. By seeing, or actually by defining and claiming it as their task to provide this evidence base in form of, e.g., systematic reviews, they promote themselves into a professional power position, but, at the same time, they delegate a self-regulating responsibility to the individual clinics and doctors when saying this evidence has to be considered for each context individually (so e.g., is the evidence applicable here, what is the motivation for your clinic, is there capacity to provide it etc.).

Furthermore, when following other accounts of these ethics committees, it becomes clear that long-term effects of ART, (in particular, that of new innovations or even experimental technologies and therapies) are the central subjects of their debate. Thus, follow-up studies are deemed to be highly important in order to reassure the public (patients as well as the professionals) of the safety and efficacy of innovative treatment options (i.e. treatments which are on their way of becoming regular medical treatments). These are, by the way, two categories (efficacy and safety) which are intimately linked together in these ethical assessments; they always appear in pairs.

For instance, in their description of one of their pre-congress courses, organized at ESHRE's Annual meeting 2021 by the two special interest groups: SIG 'Ethics and Law' and 'SIG Safety and Quality in ART' (with the title: "How safe is Medically Assisted Reproduction and how far should we go to produce children?"), they state:

> Medical assisted reproduction (MAR) involves the use of drugs and the artificial development of embryos. It has been speculated that these techniques may be associated with increased levels of long-term health problems in both patients and children. Potential health risks have been suspected ever since the first IVF baby, Louise Brown, was born in the UK in 1978. As healthcare practitioner and embryologist working in MAR, on an everyday level it seems safe to use. But is it really? Aren't we sometimes executing procedures that are quite new, **without reassuring follow-up data**? This course will consider the ideal preclinical validation path of **novel treatments** and the long-term effect on children born as the result of established assisted reproduction as well as the health effects in patients undergoing MAR. **Technical improvements in MAR pushes patients and practitioners to the limit**: Carrier-screening techniques, PGT-A, mitochondrial transfer and we will debate **how we might determine acceptable limits to new treatments**. (ESHRE, 2021; emphasis added)[81]

As we can see, generating data about and thus evidence that asserts the safety of a novel treatment becomes ever more important in the field of bioethics when assessing medical practices in ART, and above all is seemingly the *primary "ethical business"* (Pickersgill, 2012). Data collection, data analysis, interpretation of data, comparing data, the kind of temporality

[81] https://www.eshre.eu/Annual-Meeting/ESHRE-2021/Precongress-Courses/Course-4-Ethics-and-SQART (accessed on 9th March 2023).

in which data becomes produced (generated by short-term, or long-term studies) actually constitutes the evidence base on which ethical decisions are, or should be, made in an ideal case, according to the EHSRE ethics people. Moreover, related to that is the question of who actually defines what is enough and makes a firm (or even, ideal) base of evidence, and is there an authoritative instance that should evaluate all this?

From this quote, it becomes quite clear that the field of bioethics (here in case of ART), but actually EBM quite in general, might run somehow into difficulties when shifting most of their concentration on generating and assessing evidence (data) as the exclusive basis to make and justify their decisions. One has to realize that evidence, and even more so data, does not lead automatically to the right medical decisions, but the belief that it could do so reflects the hope that enough evidence could tell us how to go and in which direction to move. By referring to diverse authors who are similarly engaged with a variety of issues in the context of EBM, I have tried to highlight that there are far more dimensions and knowledges involved in biomedical decision-making than just data. Moreover, the call for EBM and evidence-based ethics respectively requires from practitioners not just to have the knowledge on how to acquire the results of current research but also the capacity to interpret and apply it in their specific clinical context. This is a difficult requirement for practitioners to implement in their daily work. But what we see here is this close nexus between laboratory and clinic, which is an important element in the transition of medicine into biomedicine. Evidence, in other words, is actually not a truth-speaking approach per se, but has to be contextualized and complemented with many other complex (value) questions and considerations that have (or should have) a say in biomedical decision-making.

6.2.2 The 'unruly nature' of technology: Technology's agency, (de-)stabilising evidence and the call for further evidence

Both organisations, ESHRE as well as ASRM, have created their own internal ethics committees, as well as a range of other governing bodies (such as special interest groups, different committees and others), who engage with diverse topics and areas in ART and produce particular kinds of documents: guidelines, guidance, and committee and opinion reports, among others. My study targets the latter ones which are responsible for developing the organizations' position on ethical issues related to ART. This also means that they obviously see themselves in an authoritative role in order to perform this kind of ethical evaluation and to provide some sort of guidance to their members and associated professionals, from a professional point of view, on how treatment options have to be categorized, assessed and what kinds can be practiced in which ways to be justified as ethically acceptable.

Because they themselves have emphasised that technological advances in this field regularly push patients and doctors to their limits, it is worth recalling Mol's understanding of technology in this respect, which she referred to as "the unruly nature of technology" (Mol, 2008). This is to express that technology is able to affect expectations that may not have existed before the advent of a new technology, meaning that technologies are much more fluid and co-produced with their environment. Bell likewise noted in her analysis of screening tests in case of PSA

(prostate tests) that technologies are 'unruly' in the sense of not just being modest means, but they are indeed *inventive mediators*:

> In the logic of choice technologies are instruments. This sounds tautological. Of course technologies are instruments. They are means to ends and the more effective these means are, the better. But what if technologies have unexpected effects? **What if they go beyond, and indeed transform, the ends they are supposed to serve? Technologies are unruly**. Once introduced into a world where they interfere in unexpected ways with lots of other erratic entities and configurations, they change much more than they were intended to, and are ultimately transformed themselves as well. Instead of being modest means, **they are inventive mediators**. (Mol, 2008: 50; emphasis added)

For this reason, it is instructive to focus now a bit more on how these ethics committees argue for *further evidence* (i.e. the need to generate evidence because of new technological developments). In this regard, we might talk about *(de-)stabilising evidence,* and the call for follow-up studies is strongly emphasized in this context. Follow-up studies basically refer to long-term studies of the health effects of ARTs for both offspring and treated women receiving the intervention, and increasingly also including third parties, such as donors. When discussing the need for follow-up studies to justify an application, it is already on the way to stabilising a new procedure. This kind of **not yet existent evidence** shows the capacity and agency of technological development and how technologies reshape already stabilised knowledge, which entails known or deemed as secure treatment options, and ultimately the whole configuration in which ARTs are embedded and practiced, too. To an extent, every new procedure (this could be a new test, a protocol, technology, medical drug …) changes the configuration and raises specific ethical questions, such as questions on rights, duties, interests, (i.e. primarily *responsibility questions)*.

As can be seen from the statements I have cited so far, the biomedical field of ART is somehow challenged in a fundamental way because it raises the general question of how and where to draw acceptable boundaries for new medical treatments and interventions. The network of existing practices in ART forms the framework in which they classify and negotiate emerging innovations and technologies. At the same time, these bioethical considerations are accompanied by a destabilizing effect on already existing and justified procedures when it comes to introducing new treatment options. Thinking about already stabilized factors (usually conceptualized as 'facts') is renegotiated in a specific sense in the process of introducing new procedures; this attempt to stabilize and categorize through the justification of new procedures constitutes the process of defining the practices and meanings of technology. This comes down to what Mol has called the *unruliness of technology*, which hangs intimately together with its specific agency and actually with the situation in which human and non-human actors come together and interact with each other. It is about how an emerging technology interacts with societal developments and other entities in its environment (which means, the broader or local situation), how it makes different values visible that are upheld in an existent (liberal democratic) society, and, in particular, that are upheld in such organizations that are potentially inclined to apply new technologies because of their role and status as scientific societies (despite the fact of lacking evidence in many cases). So, the *relation between 'facts' and 'values'* becomes topical here, their co-production, in the sense of how values become transformed

into facts and maybe even the reverse how facts – something classified as stabilised – are again destabilised and renegotiated (which I would say is the rare case, but still a virtual possibility). Furthermore, what is actually deemed to be a 'fact' and what is deemed to be a 'value'; or in Bogner's words, what is deemed as a *"knowledge question"* that actually can be adequately addressed with scientific evidence, and what as a *value question* where multiple interests are at play is not straightforward (Bogner, 2021). Bell, for instance, elaborated on how 'rights' have increasingly been invoked in relation to health. In case of health promotion around e-cigarettes, she analyses how they became increasingly framed as an issue of human rights:

> Embracing evidence-based rights is clearly a pragmatic response to altered political realities in public and global health that have accompanied the rise of evidence-based medicine, but it fosters a heavy reliance on purportedly objective claims rather than explicitly challenging the ideological basis upon which decision-making takes place (Storeng and Béhague 2013). In other words, **ethics and rights become discursively transformed into second-order issues tied to questions of evidence**. (…) advocacy becomes redefined as the translation of research into action, with proponents required to set themselves up in the role of 'neutral purveyors of evidence'. (Bell, 2017: 174; emphasis added)

With this observation in mind, we can see similar tendencies in the case of these ethics committees (and bioethics quite generally): how they present themselves as kind of 'neutral' experts, translators, or moderators on ethical issues by evaluating scientific evidence and technology. And related to this, how questions of ethics, (human) rights, and principles (including IC) are transformed discursively into questions of evidence. This reshapes not only our understanding of ethics and human rights, but also the idea of how we can approach and respond to them. This regularly leads to these concerns being reduced to technical issues and thus no longer being perceived and treated as value questions.
This reminds us equally of what Jasanoff has written a little while ago on the increasing importance and specific role of science in policy contexts:

> (…) science, because of its claims to value-neutrality, seems to provide the only forum where nations can set aside their differences in favour of a common, rationalistic approach to problem solving. To "scientize" an issue is at once to assert that there are systematic, discoverable methods for coping with it and to suggest that these approaches can be worked out independently of national or sectarian interests. Science represents for many the only universal discourse available in a multiply fragmented world. (Jasanoff 1996b: 173)

This constitutes one major salient aspect of most of these bioethical opinions, particularly with a growing trend, that ethics turns out to be something that becomes heavily scientized, so rationalised by generating, assessing, categorizing and judging scientific evidence. And at the same time, ethics also turns out to be a special kind of policy field. To this end, I now turn to another category of evidence and its evaluation, namely 'new evidence' and the question of how positions are transformed and shaped in the light of this category of evidence.

Changing positions in light of new evidence production:

Therefore, it is crucial to scrutinize a few examples of how these ethics committees deal with this category of *'new evidence'* as a particular variety of justification. It appears in these documents in two forms: either it means that new evidence suggests proceeding with a

treatment (i.e. it makes a reconsideration of a previously paused application necessary), implying a potential position change or it means new evidence could also indicate that even more evidence (so *'further evidence')* is needed. This often leads to the same result: practicing a certain treatment option only under specific, precautionary conditions and with a simultaneous demand for further data collection to provide the necessary evidence. In this context, not just the question of what should be included into the biomedical jurisdiction is of relevance but so too is the question of when a treatment is classified as experimental versus established. In the end, this is what counts: how to introduce new treatment options, or in ESHRE's (or more accurately, in the words of their ethics people), "When is the evidence base firm enough to decide that a new technology or treatment no longer needs to be regarded as 'experimental'?" (Provoost et al., 2014: 413).

In an early document (2004) on the cryopreservation of gametes and reproductive tissue for self-use, the ESHRE TF for ethics and law stated that new evidence will call for a reconsideration in the future:

> In view of the **transition time during which research becomes therapy**, **the considerations of the taskforce will need revision when new evidence is available**, specifically in the case of cryopreservation of reproductive tissues, in-vitro maturation and in-vitro follicle culture. Consent needs to be obtained within a research context rather than for therapy or preservation of fertility per se. (ESHRE TF 7, 2004: 462; emphasis added)

Back then, in 2012, it was time to re-examine and rethink the technology of cryopreservation (i.e. with all its associated practices and applications) in light of new techno-scientific developments. Previous *slow-freezing techniques* prevented the widespread implementation of oocyte cryopreservation in clinical practice because of the tendency to develop crystal formation. In contrast, new oocyte *vitrification technology* results in the complete elimination of ice crystal formation, and thus leads to better results (i.e. the effectiveness of vitrified oocytes is non-inferior to fresh ones, according to them). To demonstrate this, they present a substantial number of different studies, i.e. referring to different kinds of evidences: from large randomized clinical trials (RCTs) as a superior kind of evidence in clinical and technical terms (in the professional literature, they are often labelled as the gold standard, or as the highest evidence class: Ia, Ib),[82] over data from peer-reviewed literature, or systematic review data of observational studies, up to and including research data on attitudes towards this technology and follow-up studies.[83] This means the question becomes negotiated quite technically in the first place, which is plausible because it is about a new technique, but not exclusively justifiable,

[82] See: https://flexikon.doccheck.com/de/Evidenzklasse (accessed on 26th January 2023).

[83] "A large **randomized clinical trial** demonstrated that the effectiveness of vitrified oocytes is non-inferior to fresh oocytes in terms of ongoing pregnancy rates in an oocyte donation programme (Cobo et al., 2010). **Data from peer-reviewed literature** conclude in a 4–5% live birth rate per vitrified oocyte in women under the age of 36 years (Oktay et al., 2006; **The Practice Committee of the SART and ASRM, 2008)**, meaning that one live birth is to be expected on average per 20–25 vitrified oocytes. From the **current data**, it appears that vitrification is more efficient than slow freezing. (…) Aseptic modifications for open system vitrification, such as ultraviolet liquid nitrogen sterilization, have been described by Parmegiani et al. (2011) and recent observational data report highly efficient oocyte vitrification using high security closed vitrification devices (Stopp et al., 2011a)" (ESHRE TF 18, 2012: 2).

especially when it comes to different use cases or attitudes towards its potential applications. Of course, they also thematise other issues, but it does not change the fact too much that those more ethical, social and moral questions and issues become tied to this first order level of evidence. As far as I recognize there is not really a case where evidence reassures safety and efficacy (so the improvement of a technique) and where social or ethical concerns would lead to a halt or even rejection of a technology. Maybe the highest of feelings would be that social and ethical questions would lead to a temporary halt (as in the case of particular surrogacy arrangements in context of moral fears of exploitation) but definitely not to a general rejection of a technology (or medical intervention). The moment we start talking and caring about a technology and its possibilities, it has in a way already entered practice – and also through the discourse that is created and generated around it.

So, it is very much a question of priority setting as well as about privileged modes of justification and arguments that count as more legitimate than others. What is worth mentioning is the fact that ASRM was in this authoritative position to lift effectively the *'experimental label'* of cryopreservation in 2012, which says something about their operative decision-making power in this field. They did so in light of the above-mentioned development of oocyte vitrification as an improved technique of freezing and its respective evidence base, which caused a general reassessment of this practice:

> OC initially was classified by ASRM as experimental. In 2012, the ASRM Practice Committee removed the experimental label after a thorough review of the scientific literature. (…) While the ASRM Practice Committee and Ethics Committee approved the use of OC for patients facing therapies likely to be gonadotoxic (1-3), the Practice Committee declined at that time to recommend OC "for the sole purpose of circumventing reproductive aging in healthy women", on the grounds that there were insufficient data on the "safety, efficacy, ethics, emotional risks, and cost-effectiveness" for that indication (1). Since that time, further research on efficacy has been reassuring (4-5). (ASRM, 2018: 1023)

The last sentence demonstrates how the ethical issues (and emotional risks) ultimately become tied to the question of evidence, because evidence is that what decides, at the end of the day, if an intervention gets applied, also in these extended use cases such as reproductive aging. In another statement, they refer to ESHRE's statement and its re-evaluation of oocyte cryopreservation for fertility preservation:

> A range of viewpoints on planned OC has been presented by researchers and commentators (11, 21, 24–29). While several commentators raise questions and concerns about planned OC, most conclude it should be available to women who are fully informed and wish to use it (26, 28). The European Society of Human Reproduction and Embryology (ESHRE) approved the use of planned OC for fertility preservation in 2012 (30). (ASRM, 2018: 1024)

This nicely illustrates how they refer to each other as key issue experts (Asdal, 2015b) to justify their positions (and their change of position) in the face of new *technoscientific* developments, the evidence production around it as well as the changed expectations and attitudes of women. In this context, two excerpts from another paper[84] by ESHRE are worth mentioning, which reads as a reaction to the lifting process of the experimental status of OC by ASRM:

[84] "Beyond the dichotomy: a tool for distinguishing between experimental, innovative and established treatments" from 2014. See here: https://pubmed.ncbi.nlm.nih.gov/24430776/ (accessed on 29th August 2022).

> In 2008, the American Society for Reproductive Medicine (ASRM) had defined 'experimental procedures' as follows: 'A procedure for the treatment of infertility is considered experimental until there is adequate scientific evidence of safety and efficacy from appropriately designed, peer-reviewed, published studies by different investigator groups' (ASRM, 2008). In their 2009 and 2013 revision, the ASRM specified this level of adequate scientific evidence required to lift the label of 'experimental' for new procedures (ASRM, 2009; ASRM, 2013). In the 2013 paper it was described as 'the published medical evidence regarding their risks, benefits, and overall safety and efficacy is sufficient to regard them as established medical practice' (ASRM, 2013, p. 1197). According to this statement, procedures are thus either considered established medical practice or experimental; the latter requiring specific review of an Institutional Review Board (ASRM, 2008). In a recent statement replacing the recommendations on ovarian tissue and oocyte cryopreservation issued in 2008, the Practice Committees of the ASRM and the Society for Reproductive Technology (SART) have announced that oocyte vitrification is no longer to be considered experimental (ASRM and SART, 2013). It is stated that there is sufficient evidence on the safety and efficacy of egg freezing in order to remove the label 'experimental'. (ESHRE, 2014: 414; emphasis added)

Here, the socio-political process that accompanies any kind of knowledge production becomes visible, namely how this new technology also leads to a renegotiation of what 'adequate scientific evidence' should mean. Which, in this context, ASRM as leading authority specified as "the published medical evidence" in terms of "risks, benefits, and overall safety and efficacy". This is an intriguing instance that shows the processes of classifying, defining, naming, and thus, justifying what should count as a firm base of scientific evidence on which decisions are being made. In addition, it illustrates how ESHRE responds or reacts to ASRM's definition-making power by delineating the boundaries of how to deal with the label 'experimental' and 'established' medical practice in ART.

ESHRE proceeds by highlighting that the dichotomy between experimental and established is rather problematic because it does not necessarily reflect the reality in clinics, where treatments are offered that are neither regarded as experimental, nor established medical practice in a strict sense. They often bear an intermediate character that ESHRE proposes to call innovative, as opposed to the common usage in the literature as something that has not (yet) been scientifically researched (Provoost et al., 2014). The idea behind the introduction of this intermediate stage of *innovative treatment* is that centres or clinics offering such treatments should feel a greater obligation to collect and review (follow-up) data about their patients and children.

Accordingly, in this paper they develop (in response to ASRM's Practice Committee) a three-dimensional scoring tool that reflects the progression of a "new procedure from experimental through innovative to established", based on four criteria, including: efficacy (categorical: showing proof of principle, or not: pass or fail); safety (regarding both, patients and embryos); procedural reliability and transparency (implementation criteria: similarity or variability of the procedure in different laboratories); and effectiveness (likelihood of producing the desired outcome compared to conventional ART techniques) (ibid.: 415). Further, they argue:

> Given that our account of three phases is an ideal model, the continuum should be treated in a flexible way, so as to realistically reflect the development of techniques in practice. For instance, it is possible that, for a certain procedure, there was no distinct experimental phase. Sometimes, practice rather than research has led to sufficient data on which a decision can be made to regard a new technology or treatment as innovative rather than experimental. The introduction of oocyte vitrification is an example of

this. Also, an innovative treatment could be (and should be) invalidated when found unsafe, ineffective or otherwise problematic. (ibid.: 416-417; emphasis added)

What is remarkable about this discussion is how they refer to each other as key issue experts (Asdal, 2015b), and how they attempt to situate this very discussion in their institutional domain when they assert that the development of such a scoring tool to classify treatments and clarify the boundaries between research and treatment (or identify graduations) should be used at the macro level by professional societies. Moreover, by developing this tool, ESHRE is obviously trying to defend its leading position and even perhaps to demonstrate a 'European' approach towards this issue in a different (or as they would call it, "non-dichotomous") way.
Further, both emphasized the practical way through which this new technology of oocyte vitrification has found its way into common medical practice and not through research, which is interesting because they argue retrospectively that scientific evidence and research should be the main base on which these decisions are being made. In any case, it shows the strong intertwinement of practice and research in this biomedical field, through which the different domains involved, such as ethics and science, are rearticulated.

However, what can be concluded at this point is that their positions are not 'merely opinions' which follow some principles, but rather are a legitimate position that is justified exactly because it is based on empirical evidence. But why is this so convincing? Because scientific evidence becomes constructed as a supposedly objective, technical measure, which is (quite tellingly) captured in a section called 'Background and facts' in the opinion papers of the ESHRE TF. This fits well with the general, rational logic of principlism and its inscribed idea of the inventors to refine, correct and specify continually (and one might add here, to legitimate) bioethical decision-making and these very principles. In addition, the naming of a section as 'Background and facts' is an interesting instance of boundary work, in which they try to distinguish, or even more accurately subordinate, the 'ethical' issues from that what is already deemed or seen as stable, known and undisputed, and thus that which does not require further justification. The underlying claim presented here is that the presence of reliable evidence, especially numerical evidence, ensures automatically better biomedical decisions.
Nevertheless, in the process of medical decision-making, a broad spectrum of knowledge is at stake, as has already been pointed out with Goldenberg (2005): reaching from the multiple dimensions of evidence, over personal experience and values, to economic and political considerations as well as philosophical principles. Biomedical decision-making can never be fully free of value judgements: "Normative content seems to enter at all levels of decision-making, even in the production and presentation of the scientific evidence that is supposed to univocally inform evidence-based decisions" (ibid.: 5).

6.3 Acknowledging ethical pluralism: Informed consent and principle-based ethics as further argumentative modes of justification

(…) modern societies have steered away from a globalizing representation which manages to integrate all differences, and have recognized the existence of a plurality of modes of legitimate evaluation. This acknowledged pluralism puts pressure on the actors who, depending on the situation, have to come to an

> agreement with different principles of justice. (…) The double observation, first of a diversity in the ways of justification or criticism, and simultaneously of a capacity of persons to go from one to the other, incited us to systematically confront the forms of justification that are in use. (Boltanski & Thévenot, 2000: 218)

In this statement, Boltanski and Thévenot describe the general move towards the recognition of ethical pluralism in modern societies. Hence, ethical pluralism as a fundamental social value is not just an abstract entity but is actually something that takes place in everyday life, performed in mundane practices of justifying, negotiating, agreeing on different principles of justice, and, so too, in these ethics committees and their ethical opinions.

Both ethics committees have established undoubtedly specific normative frameworks, which combine different justificatory strategies and ethical approaches in order to work through specific ethical and legal issues in the field of ART (issues that are often framed as controversial) and, in the process, also produce moral truth(s). So far, I have concentrated on evidence, but there are also other approaches, such as *principle-based* arguments and *informed consent* (IC), that are employed when justifying practices in ART from their professional perspective. For this reason, I elaborate on these two further modes of justification those ethics committees regularly base their decisions on.

As the previous chapter detailed, in these papers, scientific evidence operates as a dominant and supposedly neutral or objective mode to justify, and thus to decide in technical terms, what should count as ethically (and morally) acceptable practice. Evidence seems to be the device that is deemed as the necessary scientific underpinning to these other two modes of justification. However, these other two modes have now a slightly different scope: principles and informed consent, the latter meant as the medico-legal protection of the autonomy principle, can be seen as two sides of the same coin, or actually as two variants of the same mode of justification, with which both societies try to *acknowledge the value of ethical pluralism*.

In what follows, however, I will speak of *two modes* of justification because this notion points exactly to the fact that it makes discourses multiple and mobile – "it invites a comparison of different ways of thinking and acting that coexist in a single time and place" (Mol, 2008: 9). ESHRE's ethical considerations are characterized by an emphasis on different *ethical principles* that need to be balanced (with a strong focus on the *'welfare of the child')* and different perspectives on ART issues. ASRM's ethical considerations likewise stress the importance of making and hearing different perspectives, but focuses, in contrast, more on the importance of providing (evidence-based) *information* to the patient to enable autonomous decision-making. To this end, ASRM's statements focus very much on the principle of patient autonomy or, in this particular case, '*reproductive autonomy'* in its practical operationalization (informed consent).

These slightly different modes of justification point to a different practice of ordering, both of which attempt to come to terms with the recognition of ethical pluralism. In this chapter, I focus specifically on how these two modes of justification become used in these different institutional settings, how they are linked to each other and, especially, in what ways they are introduced and how they are interrelated with scientific evidence as central (but different) mode of justification in these opinion papers. The relevant point here is to highlight, on the one

hand, how those rather *common approaches* that are used to tackle ethical issues become *performed* in these specific cases, and on the other, how they are tied to questions of evidence. This is relevant regarding their functionalities and the role they fulfil in terms of the principles of justice expressed through them.

I start with an analysis of the informed consent as a fundamental bioethical response to justify the ethicality of ART practices by focusing especially on ASRM's take on. I do this because it is their privileged mode to ethically justify the implementation or adoption of new treatment options. The procedure of informed consent is a well-known and established technique in medical practice to protect autonomous decision-making,[85] and *here* in these opinion papers, it indeed operates as a dominant *justificatory argument*. Then, I continue with an examination of the principle-based approach by concentrating on ESHRE's version, because it is their preferred mode to justify the ethicality of ART practices. This is done through a comparative lens, i.e., I regularly juxtapose one case with the other case as this provides me with the point of contrast or reference for a particular site and vice versa. In this way, one increases one's sensitivity to each case by developing an understanding of its particularities, but without losing sight of its generalities at the same time.

6.3.1 The autonomy principle and its translation: The informed consent as a dominant justification for self-regulation

The process of *'Informed consent'* (IC) can indeed be seen as a central mode of justification in biomedicine, one that forms the operationalization of *patient autonomy* (referring to autonomous decision-making). The IC constitutes a particular practical answer, or the specific practice through which most of bioethicists and medical professionals consider the principle, (in this case, of reproductive autonomy but sometimes also referred to as liberty, to which I will return in chapter 7) to be almost fulfilled when including all relevant – and primarily evidence-based – information regarding treatment options on a consent form.

There are basically two key differences that bioethicists, especially in case of ASRM, are discussing when it comes to the informed consent form: first, IC obtained in a *research context* and, second, IC in context of *reproductive treatments*. Of course, this is not just a question in reproductive medicine and ART, but quite generally when it comes to new treatment options in biomedicine (be it a new medical drug, medical technology, a related treatment procedure, or protocol).

Although, in this case, these two areas of application are considerably intertwined, because human tissue material is always generated through IVF treatments, primarily gametes and embryos. Subsequently, the question arises of what might be legitimately done with the so-called 'leftover material'; there are two options of what might or should it become, either a *research object* or a *treatment object* for reproductive purposes. The ASRM ethics group, and certainly not only they, are trying hard to keep these two areas, or possibilities, apart, especially when it comes to the informed consent; however, this is not always an straightforward task

[85] I will return to some of the critique and problems associated with the IC in Chapter 7, in which instances it is too myopic and reductively practiced or argued.

because these uses are often intermingled. Nevertheless, in their logic, it is crucial to distinguish between them, i.e. to consider what the respective IC must look like, and what information it must contain in each case in order to be ethically justifiable.

This means, when it comes to IVF and its related technologies, including embryo research as a possible connected research area, the IC is closely related to the question of human tissue material and its processing *as an object of research*. Hence, they introduce some aspects which would exclude specific purposes from the outset when it is not included adequately on an informed consent form. This means, they are pondering with a substantial number of different scenarios and deciding which kind of information must be included on which consent form. For instance, embryos or gametes that have become research objects are excluded from further use for reproductive purposes (e.g. in case of gene editing). This means if the consent form explicitly states that the generated embryos and gametes are exclusively permitted for research purposes, it is deemed unethical to use them for further reproductive purposes since this would represent an instance of involuntary procreation. In the context of the use of gametes and embryos for research purposes, the ASRM ethics committee has produced a considerable number of ethical opinions on the IC, to which I refer alternately in the following (from 2014, 2020 and 2021).

Sometimes these organizations argue for practicing 'experimental' – or let's say rather emerging (or as ESHRE has put it, 'innovative') – procedures in 'secure' settings, which means those conducted under specific framework conditions. This quite often boils down to the practice of informed consent as a fundamental technique to secure autonomous decision-making for participation in such settings. The ASRM ethics committee, for instance, has stated in an earlier opinion paper titled "Moving innovation to practice: a committee opinion" from 2015, the following:

> **Collaborative decision-making** and **informed consent** are fundamental components of good clinical practice. When treatment choices are made, the **conversations between patients and providers** should include a discussion of a range of factors that will influence patient choice. Patients who have struggled to build a family are particularly **vulnerable** to the offer of treatments and procedures that appear promising, and they may have difficulty appreciating uncertainty about effectiveness and risk. They may be willing to ''try anything'' and have difficulty saying ''no.'' These factors, combined with the high value placed on **reproductive liberty** in fertility care, **make the decision-making process a challenging one** (…). A patient should be informed if the intervention, whether a test, laboratory technique, drug treatment, or surgical procedure, has been recently adopted by the practice. The provider should share **evidence relevant to the expectation** that the new intervention is likely to be successful for the patient, and how risks may differ from those of standard treatment. (ASRM, 2015: 4; emphasis added)

This opinion paper represents an important and recurring reference point in their discussions, because it constitutes a rather general paper that is thought to apply to many other concerns in the field. Particularly interesting here are two things: first, how they outline the IC as a kind of procedural technique because it is situated in the context of a collaborative decision-making process, which is characterised by conversations between patients and providers in which treatment choices are discussed. In this context, the understanding of the information by the patient is essential as well as the relation with the notion of liberty, (however, I will return to these aspects in further detail in chapter 7). And second, how this deliberative IC process

becomes related, or hinged upon the provision of scientific evidence, so reliable information. Namely in form of the suggestion that professionals should share evidence that is relevant in terms of patient expectations, including, for instance, what outcome or possible risks the patient can expect from a new treatment option.
ESHRE, for instance, has similarly recommended regarding the IC in case of oocyte cryopreservation in a paper from 2012 (two particularly relevant recommendations are provided here, however, their entire list entails eleven of such recommendations):

> (vi) Interested women should be adequately informed about all relevant aspects of the procedure for obtaining the oocytes, the conditions for storage, time frame for reproductive use and the options for deciding about the eventual fate of any left-over oocytes.
> (vii) Interested women should be informed that oocyte cryopreservation is a relatively new technology, that the number of children born from such oocytes is still limited and that long-term safety is still to be proved. (ESHRE TF 18, 2012: 6)

Thus, how informed consent becomes tied to evidence is illuminating: an adequate IC (conversation) has to include evidence about the safety, risks and success rates of this new technology. It is further striking that these aspects become particularly emphasized in the context of relatively new, or emergent technologies. That is, when it comes to the application of new or emerging technologies, scientific evidence (i.e. its production, evaluation and presentation) becomes an important issue of justification, although the evidence itself is largely lacking because data are limited. This shows the high value placed on empirical evidence and this type of argumentation to justify the respective treatments, even though it is considered necessary to make patients aware of the fact that there is currently (or at a certain point in time) a lack of evidence and thus actually a lack of justification.
However, this is then justified by the practice of informed consent and the decision is left to the patient in the sense of the principle of reproductive autonomy. This also draws our attention to the thorny issue at stake here: the *question of responsibility*. So, who should actually take responsibility and on the basis of which evidence should a decision be made, and by whom? This mainly concerns the definition of adequacy of the evidence base. And further, how should this responsibility be distributed? Which is a keyword that ASRM tries to capture somehow with the notion of "collaborative decision-making", which constitutes a particularly tricky one in fertility care, but not just here.

Yet, I will continue with some observations I have made during my document analysis of a quite recent paper called *"Ethics in embryo research: a position statement by the ASRM Ethics in Embryo Research Task Force and the ASRM Ethics Committee"* (2020). Embryo research is generally a much-debated research field (both within the scientific community as well as in public debate and media), but is currently re-gaining particular momentum as some researchers have recently succeeded in keeping human embryos alive in a dish for up to 13 days, as this quote shows:

> (…) they then terminated the experiments in accordance with the 14-day standard. Such advances have led some ethicists and researchers to argue that the decades-old rule is antiquated and ripe for revision. Allowing embryos to grow past 14 days, researchers say, could produce a better understanding of human

> development, and enable scientists to learn why some pregnancies fail, for instance. The revised ISSCR (International Society for Stem Cell Research) guidelines are a prompt to begin conversations about when it would be valuable to grow embryos beyond 14 days, says Alta Charo, a bioethicist at the University of Wisconsin Law School in Madison, who was part of the ISSCR steering committee. "We didn't debate it before — now it's time to debate". (Subbaraman, 2021: 18)

Here, too, we are dealing with a technoscientific development that has initiated a re-evaluation of a reproductive technology, namely embryo research (with the main issue being embryo cultivation beyond 14 days). Against the backdrop of a varied legal background and diverse statements and 'rules' (such as guidelines, recommendations and consensus papers) published by other institutions in this field, it is clear that ASRM and ESHRE need to develop their own position on this controversial line of research, because this is an important element of self-regulation. These developments have urged these scientific societies to re-evaluate and discuss the issue on a regular basis.

In this context, ASRM as a scientific society considers this particular research field and its many possibilities anew. As a *practical principle*, the informed consent occupies a prominent role in embryo research, particularly in the US context, because it sparks numerous inner-scientific as well as public debates or even controversies. The legal specificities of embryo research are of great importance for ethical considerations because they indeed affect its possible scope of action (experimenting and application), especially in terms of its funding. This includes which lines of research are actually funded on which level: government (state) or private funding possibilities. It is hoped that through the IC process – as a kind of self-regulatory device – most of the ethical issues can be addressed and resolved.

The ASRM has specifically formed a Task Force that deals exclusively with the ethics of embryo research, but is in constant contact with the ASRM ethics committee:

> Cognizant that research in reproductive medicine can involve human embryos, in 2017 the ASRM Board of Directors established the Ethics in Embryo Research Task Force (the "Task Force") to consider, debate, and ultimately draft the present position statement addressing ethical considerations in embryo research. The Task Force's efforts were to include ongoing consultation with the ASRM Ethics Committee (the "Ethics Committee"), a multidisciplinary group established over 30 years ago to provide guidance on ethical issues arising in the field of reproductive medicine. This position statement is a product of the collaboration between the Task Force and the Ethics Committee. (ASRM, 2020: 271)

This is an interesting instance where they provide insights into their deliberative approach, including their approach towards task sharing and collaboration between the two involved working groups. This signals that the profundity of the issue requires a separate group within the organization to consider exclusively the ethics of embryo research. Especially in light of the transformation and developments that have taken place in the field of embryo research (as already mentioned in the quote, the International Society for Stem Cell Research, for instance, relaxed the famous 14-day rule on culturing human embryos in its latest research guidelines).[86] It further shows that the ASRM ethics committee is obviously concerned with numerous other questions and topics in the production of its regular opinion papers, but is nevertheless

[86] See, e.g., Subbaraman 2021, https://www.nature.com/articles/d41586-021-01423-y, (accessed on 14th October 2021).

involved in this consensus paper because of the long-standing ethics expertise within the organization. The case of embryo research and the related relaxation of the 14-day rule of embryo culturing in the lab also points to the fact that successful experiments, so scientific evidence, paves the way for permitting (or relaxing) a thus-far forbidden procedure due to its previously mere-theoretical status. Formerly, it was simply not possible to culture human embryos for such a long time in a laboratory setting. Again, new scientific evidence made this reassessment necessary.

This recent paper on ethics in embryo research, that was co-authored by the ASRM Ethics in Embryo Research TF and the Ethics Committee (2020), sets out some general and a number of specific considerations about IC processes in the light of these new scientific developments. In a research setting, it states that the IC is an "essential and indispensable process prior to any use of embryos" (ASRM, 2020: 283) by those who have dispositional authority over embryos, addressing the patients who have been given this power of disposition as part of the donation process. In the usual case, the donor relinquishes their authority over the material during the donation process and passes that authority over to the recipient (most often called the 'intended parents'). In this regard, they introduce a further interesting concept called **"broad consent"**, which makes an attempt to tackle the issue of unclear future research uses. They clarify what 'dispositional authority' means in this particular context:

> This mechanism may give clinics an important new option to enable non-reproductive research involving embryos that can be identified. Under the broad consent mechanism, individuals could consent to any subsequent research use of identifiable tissue samples. At this point, the distinction between non-reproductive research and research in which reproduction is intended is critical. (…) Given that embryos have reproductive potential, and that individuals should never be compelled to reproduce without their knowledge or without their consent, any embryo research with reproductive intent should only occur with the explicit consent of the individuals who have dispositional authority over the embryos (this may be the gamete providers or, in the case of gamete donation, the gamete recipients/intended parents). (ibid.: 282)

The *category of broad consent* is interesting because it is an *anticipatory* one that tries to capture future research uses that are not yet (or at the specific time when consent is obtained) existent but can just vaguely be imagined from current developments. What is also clear is that not every particular arrangement, or research purpose, can be foreseen from the beginning, for instance, when it comes to emerging technologies and research lines that have not been previously known. This is an aspect they mention in the context of gene-editing technologies and its research:

> Whether such broad consent also applies to research uses that involve the derivation of stem cell lines or the alteration of the genetic makeup of an embryo has not been established. **Ideally, the initial consent** that occurs at the time that the gamete is donated **should include all potential future uses** of the embryos produced from the gamete donation. **This becomes complicated when research directions that could not have been envisioned at the time of the gamete donation become a reality**. **Such complexity should be included in the initial consent process**, and allowances should be made (…) to opt out of specific future uses (…). (ibid.: 283; emphasis added)

What they further elaborate on in their report is the possibility that donors may stipulate which kinds of research they deem ethically acceptable for their donation, or which ones they want to exclude, which is an interesting construction in light of unanticipated research directions.

This ideal consent mechanism somewhat constructs the idea as if it were possible to anticipate all possible research directions, even ones that are not yet imaginable, but the consent should reflect those complexities (or one might say uncertainties).
However, to some extent, it is also a too easy move to include just a vague phrase on the consent form authorizing as yet unknown future research directions because it does not really allow the donors or gamete recipients (those with dispositional authority) to make a differentiated decision. What is still unknown cannot simply be anticipated (otherwise it would be known) and is therefore difficult to include into an informed consent form. Anticipation only works in light of already known or imaginable (virtual) practices, indications or reference points. What is expressed here, however, is a desire to regulate this uncertainties through a profound power-knowledge complex to which Foucault already drew attention, a profound incident of the co-production of the will to knowledge and thus to power.
Nevertheless, a prerequisite for the broad consent is that the IC should be as specific as possible and at the same time all-encompassing about current research plans; this also would allow some patients to opt out of specific research plans they deem ethically unacceptable to them. In the following, they list six aspects they deem essential to include in an informed consent form in context of hESC research:

> When derivation of human embryonic stem cells (hESC) from the donated embryos is the intent of the research, this information should be included in the informed consent process **[1]**. Such consent should make sure that the donors are aware that the removal of the inner cell mass of an embryo for the derivation of hESCs leads to the destruction of the embryo **[2].** It should also inform the embryo donors that cell lines may be stored indefinitely **[3],** and used for multiple research projects, and be shared among more than one investigator **[4].** They may be used for basic research and/or to develop new drugs, tests, treatments or products that could have potential commercial value **[5].** As part of the consent process, embryo donors should be informed that they will not derive any direct benefit from research performed on their donated embryos **[6]**. Embryo donors should be reassured that their donated embryos will not be used for reproductive purposes. (ibid.: 283; numbers in brackets added)

Within a seventh point, they refer to the importance of reassuring the donors about the purpose of the donated embryos; if those embryos are donated for research purposes, it has to be absolutely clear and obligatory that they are not used for any reproductive purposes because this would almost border on misuse (because it would entail unwanted and unknown procreation). This shows, on the one hand, that with any further iteration, the arrangement becomes messier[87], i.e. that any possible or rather expectable constellation should be in the ideal case considered at the beginning of generating tissue and material.
In the case of ASRM, this basically means that all of these issues and questions are integrated into the consent process, making this research endeavour a justified ethical practice. With regard to the *ethical acceptance*, the ASRM seamlessly shifts this question into the domain of the IC, i.e. the patient authority: ultimately, the patient should decide which (if any) usages should be ethically acceptable to them or not. On the other hand, the framework within which

[87] Particularly in context of third-party reproduction that includes e.g. gamete donors and involves sometimes complex constellations and questions. One reason why different professionals in this field would argue for treatment options (and also new technologies) in which donors are not necessarily involved (if it is avoidable), because complexities that these arrangements entail – be it of psychological or physical nature - can be bypassed.

this decision is made is already set by the respective IC (ASRM, or by a clinic, or research institution, which may be bound by such professional guidelines). The 'only red line' that ASRM clearly draws is that embryos donated for research purposes are excluded from any further reproductive use from that point onwards.

Questions of ***privacy and anonymity*** are complex matters as well when it comes to tissue donation because they can never be fully guaranteed – a fact which constitutes an essential information that donors need for their decision-making. Simultaneously, as the statement above explains, they have to be informed that they will not inevitably be alerted to information learned from their genetic material, which could be perhaps relevant to them. On the other hand, genetic information gathered from research on embryos may affect the donors, their family members and their offspring in different ways, so it is necessary that they have also the option of not receiving such information. Consequently, donors of the embryo must give "consent to relinquish all rights and interests to their donated gametes once the gametes leave their bodies" (ibid.).

In this regard, they mention a further form of an IC process, a so-called **"roll-down consent"** that applies particularly to the situation or constellation that involves third-party reproduction. Here it is about resolving the question of dispositional authority over the gametes, or embryos, within a donation process. The idea is that gamete donors give broad consent to future research purposes after the gamete recipients have used the resulting embryos to complete their family plans: "This consent would specify that the ultimate disposition of the embryos would be determined by the gamete recipients at a future date once they no longer require the resulting embryos for reproductive purposes" (ibid.: 283). The only exception again would be research use that includes reproductive intent, because without knowledge or consent of the initial gamete providers, this would constitute involuntary procreation, and this constitutes ineluctable and unacceptable practice, according to ASRM. However, what is particularly instructive here is that through this roll-down consent practice, the authority over tissue material (which means the embryos) is already determined. They define who should have the right to decide their fate and who should not when it comes to the use of embryos for research purposes. At least they argue that during a donation process the full dispositional authority over the donated embryos should pass over to gamete recipients (and not the donors).

As can be seen from these examples, the IC can definitely be considered as one of the main (argumentative) resources through which practices in ART become justified as ethical acceptable, especially in the case of the US-based organization. It is there where it appears in almost every single paper as a prominent mode of justification. Therefore, I will proceed with some relevant issues that they outline when it comes to questions of who, how and in which form the consent should be drafted. This also includes the diverse oversight mechanisms or structures in which the consent is, or should be, embedded. In doing so, I focus both on the previous paper on embryo research and on the following two ethical opinion papers, *"Defining embryo donation: an Ethics Committee opinion"* (from 2016) and, *"Informed consent and the use of gametes and embryos for research: a committee opinion"* (from 2014), both of which are from the ASRM Ethics Committee.

As one can easily glean from these papers, the consent process becomes particularly relevant in the context of reproductive treatments where gametes and embryos are generated, and which is followed by respective research endeavors and the question of usage of this material. As a matter of course, also papers on third-party reproduction, or papers dealing with questions of innovation and innovative treatment options (emerging technologies) also contain various considerations of the IC, but not necessarily to the same depth as the papers on the use of tissue material for research purposes in reproductive medicine[88].

One general complexity of the informed consent process in this research arena originates from the fact that embryos and gametes are used in a research context, which were originally generated in the course of a reproductive treatment – these two things are intimately entangled in the field of ART. However, this affirms what Foucault has already noted in his book "The birth of the clinic. An archaeology of medical perception": the modern medical gaze does not merely apply a kind of knowledge, but produces knowledge; the clinic is not merely a space of applying knowledge, but precisely a space of producing knowledge – the medical gaze is thus also one of power (Foucault, 1973). In this regard, Petra Gehring concretized:

> It is this knot of discourse and non-discursive practice that matters to Foucault: in an institution, the practice side of discourse and the discourse side of practice interpenetrate each other – just as [in an institution] the power side of knowledge and the knowledge side of power interpenetrate each other. (Gehring, 2004: 111; translated by the author)[89]

Further complexity arises regarding the different kinds of tissue materials as well as their particular characteristics, with which simultaneously specific questions arise. For instance, in their opinion statement from 2014 on the use of gametes and embryos for research, ASRM lists the following cells, embryos, or tissues which are relevant to consider in this regard:

> (…) oocytes, spermatozoa, nonviable or abnormal embryos, abnormally fertilized embryos that will not be transferred to the uterus, normal fresh or frozen embryos donated by IVF patients who no longer wish to use the embryos for reproductive purposes, ovarian tissue, testicular tissue, or gametes obtained to generate research embryos but never intended to be transferred. Sensitive ethical and policy issues arise when research involves the destruction of existing viable embryos or the generation of embryos for research that involves their ultimate destruction. This committee recommends informed consent for use in research should be obtained from each cell or tissue donor before any research activities are carried out on any of these cells or tissues. IRB approval is required for all such research. (ASRM, 2014: 333)

It is a broad range of reproductive bodily material that might result as part of infertility treatments and thus, be used in this rather sensitive research area, especially with regard to the production process. They differentiate here between *three categories* of producing this particular material: *first*, so-called 'left-over' material, (which is mainly designated as

[88] Quite often they refer in other papers exactly to these papers because it is here where they detail the various aspects of the IC process and its different methods in diverse contexts, including, for instance, considerations of the regulatory frameworks in which the IC is or must be embedded in the US.

[89] The original quote is in German and reads as follows: "Auf diesen Knoten von Diskurs und nichtdiskursiven Praxis kommt es Foucault an: In einer Institution durchdringen sich die Praxisseite des Diskurses und die Diskursseite der Praxis – ebenso, wie sich in ihr die Machtseite von Wissen und die Wissensseite von Macht durchdringen. Wissen und Macht sind zutiefst untrennbar. Sie sind entfaltungsverwandt, sie treiben einander hervor, sie können sich gegenseitig steigern" (Gehring, 2004: 111).

'abnormal' and, in any case, is material which was originally generated for reproductive intent but which will not be transferred to the uterus because of its genetic anomalies); *second*, normal (fresh or frozen) embryos donated by patients who no longer wish to use them for reproductive purposes; and *third*, gametes or embryos generated extra for research purposes. In the remainder of the paper, they address in detail the various aspects of informed consent for embryo research and conclude that consent should be obtained for each individual cell or tissue on which research activity is to be conducted. This must be done in accordance with an Institutional Review Board (IRB) approval, which is mandatory for (embryo) research in the US. This is one of the starting points for their discussion on the approaches to oversight mechanisms of such delicate research activities and therefore it is necessary to put it into this context:

> The primary oversight mechanism for research involving human subjects in the U.S. is the system of institutional review boards (IRBs) established by the federal Common Rule. As outlined below, the Task Force recommends use of the Common Rule/IRB framework for research involving embryos, even when the facility conducting the research falls outside of structures in which the framework is legally required. (ASRM, 2020: 281)

The Common Rule is a multipart federal regulatory scheme first promulgated in 1981, which governs the protection of human subjects in biomedical research. In this context, the IRBs are the main oversight mechanism in the US for research involving human subjects and which were established by the Common Rule. The main question addressed by ASRM's ethics people in this regard includes the aspects for approval, review, consent and reporting in embryo research and whether it is necessary to develop a new oversight structure specifically for this type of research or if it is appropriate (and justified) to rely on the existing legal framework.
Their recommendation is that all facilities, even those which fall outside of these structures, should apply the existing legal framework. That means this particular regulatory structure is not mandatory for clinics or institutions which are not federally funded, however, ASRM recommends that they too follow that framework:

> (…) many larger institutions, such as academic medical centres, choose to apply both the Common Rule and the FDA requirements to all the research they conduct and make assurances that they are doing so to the federal government. (…) Clinics falling outside these structures would not be legally required to follow the Common Rule but in the judgment of the Task Force should be encouraged to do so. (ibid.: 281)

They further clarify the difference between the Common Rule and the US FDA (Food and Drug Administration) requirements, which are relevant in this context because those rules affects directly their main justificatory argument:

> A primary difference between the Common Rule requirements and the FDA requirements is that the latter impose more stringent expectations for informed consent. (…) However, many larger institutions, such as academic medical centres, chose to apply both the Common Rule and the FDA requirements to all the research they conduct and make assurances that they are doing so to the federal government. (ibid.: 281; emphasis added)

In context of the federal Common Rule, they explain an important aspect regarding what 'research' actually means, i.e. how it is defined here. This is of great importance, because this (legal) oversight mechanism only applies if it is research in the sense of this definition:

> The definition of "research" is important for understanding the scope of the federal Common Rule. "Research" is "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge" (38). The variety of quality improvement activities conducted by clinics is not research under this definition, and thus would not require IRB review. However, under ASRM Ethics Committee opinions patient consent is required for the use of embryos in quality improvement efforts by clinics (41). (ibid.: 281)

Here, in fact, they claim some kind of authority in the field and therefore claim responsibility as an instance of self-regulation when they assert that, according to the ASRM ethics committee, patient consent is also required for embryo research in quality improvement studies by clinics; and, as already mentioned in chapter 5, most clinics are ASRM and SART members, where they must adhere to their 'Code of Practice'. The next basis for applying a more or less 'rigid' oversight mechanism to embryo research goes back to the fact that it has this particular *controversial potential*, or as the ASRM ethics people put it:

> In the judgement of the Task Force, oversight of research involving embryos should occur in a consistent manner across all facilities that perform human embryo research. Embryo research has the potential to be ethically complex and politically controversial. Because there are differing judgements involving the status of the embryo, as discussed in the first section of this position statement, these controversies attend all embryo research, whether or not it is conducted with reproductive intent (ibid.: 281)

The ASRM ethics committee and the task force for embryo research – and ESHRE, by the way, – take the same position of the *"embryo as potential",* "(…) wherein the embryo is neither perceived as a person, nor as a property" that are the two other positions around which a "consensus has emerged shaping the debate" (ibid.: 273). The 'embryo as potential' defines the preimplantation embryo (i.e. the embryo which is not implanted yet); it is the entity that the debate is all about in assisted reproductive medicine:

> (…) occupying **an intermediate position between a human person and human tissue**. Accordingly, it is **entitled to special consideration** because of its potential to become a person and its symbolic meaning in the landscape of human development. The moral and legal parameters surrounding the concept of special consideration are less well-defined than in the person/property designation, and thus require principled guidance to avoid ad hoc **decision-making in the research arena**. (…) **it is this concept of potentiality that drives the range of viewpoints on the acceptable treatment of embryos in the research setting**. (ibid.: 273; emphasis added)

It is precisely this particular definition of the pre-implantation embryo (an intermediate position between a human person and human tissue and its potentiality and symbolic meaning in human development) which represents a powerful moment of issue-making through modification that opens up the space for self-regulatory mechanisms. As a result, the situation is less clear how to deal with an 'embryo as potential' at an ethical, medical as well as legal level. As they rightly point out, the case would be much clearer if one would go with one of the well-defined person/property designations. However, the diverse complexities involved in dealing with this special entity and the borderlines between research and reproductive

treatment establish precisely areas of tension and conflict in the field of reproductive technology:

> Many important scientific questions regarding human reproduction, development, fertility and regenerative medicine can only be answered by research involving human embryos. (…) Human embryos have a number of unique characteristics that can only be understood by investigating the embryos themselves. (…) A complex cascade of gene expression needs to occur for the activation of the embryonic genome. Research on early stage in vitro human embryos holds the promise of improving our understanding of the molecular, cellular, genetic and epigenetic mechanisms that control the development of early human embryos. No surrogates for human embryos exist for this type of research. (ibid.: 277)

Again, the *potentiality of this entity* – the in-vitro human embryo, or: preimplantation embryo – and its accompanied research field are insofar interesting, because its uniquely attributed characteristics operate as general justificatory narrative. In this narrative, the research is embedded and simultaneously forms the very object at stake – the unique embryo and its promising research field.
Hence, these scientific societies try to frame and shape debates and issues in specific directions for two particular reasons: firstly, they do this in ways that takes account of value plurality on the one hand, but also, secondly, in a certain way in order to claim professional authority and thus, definition power over treatments and research around this unique entity. In this sense, it is a case of boundary work and thus a self-regulating moment, in which the value of science and its progress is strongly emphasized. However, in one of their papers, ASRM conclude:

> The informed consent process and informed consent forms for donors should receive prior approval from the IRB or equivalent oversight committee and include the information deemed appropriate by the Society for Assisted Reproductive Technologies (SART) and ASRM. (…) In summary, a carefully specified procedure for obtaining informed consent is vital for the ethical implementation of studies involving human gametes and embryos. (ASRM, 2014: 334)

But it is the informed consent process which functions as the regularity of its discursive practice, which justifies the very ethical performance and adequacy of this research practice; but in this sense, it is also a rather technical response to these complexities with their attendant value questions.

In the following, therefore, I proceed with a short comparative recap of ESHRE's position towards the in-vitro embryo, since they approach it slightly differently, namely rather in a *principle-based* manner. This actually constitutes a good entry point into analyzing their primary mode of justifying ART practices to further elaborate on what this particular mode of justification entails, how it is tied to questions of evidence, and how it relates to the IC concept.

6.3.2 The rationality of the principalist approach and its governance function

Regarding the in vitro embryo and its specific characteristics, and similar to ASRM, EHSRE stated in their very first task force document published in 2001 on "the moral status of the pre-implantation embryo", a paper which serves as a recurring reference point for the ASRM and its ethics committee in other publications, it states:

> However, in order to avoid confusion and specialized terminology which may lead to uncertainty in the public mind, and with the knowledge that there are many other definitions for the entity resulting from fertilization during development to the fetus, we have decided to use the generic term 'embryo' which refers to the stages from fertilization to the formation of the embryonic disc. (…) However, the main point is that the pre-implantation embryo is human and deserves our respect as a symbol of future human life. Thus, the following remarks apply only to the pre-implantation embryo or the embryo before it is transferred into a uterus, the actual step that may lead to the birth of the child. (EHSRE TF 1, 2001: 1047)

As one can notice, they already took the same position as ASRM in 2001: "the embryo as potential", an entity with a status between a human person and human tissue (as ASRM has put it) and which basically means that it deserves, as ESHRE pointed out, our respect as symbol of future human life. Consequently, it can be concluded that this is now a generally accepted position, at least within this biomedical profession. This position, or conceptualization as potentiality, enables and drives "(…) the range of viewpoints on the acceptable treatment of embryos in the research setting" (ASRM, 2020: 273). As a further justification for the need for embryo research, ESHRE has made clear that this is exactly the kind of research that actually formed the basis for the beginning of IVF:

> (…) pre-implantation embryo research was necessary for the advent of IVF, and is necessary for the continuation of the care of infertile couples to an ever-improving standard. It is also useful in other fields linked to reproduction (e.g. contraception) and for fundamental research.
> Research embryos should not be transferred to achieve a pregnancy. However, in the transition between research and therapeutic application of the technique, there must be reasonable indication that this technique will not harm the child to be. (ESHRE TF 1, 2001: 1048)

With regard to the 14-day rule, they already formulated back in 2001 that it has to be re-evaluated on a regular basis, for specific cases, and in light of new scientific developments. Since the 14-day rule is somewhat arbitrary because it was difficult to determine an acceptable limit, the ethics group of ESHRE has clarified:

> The 14 days limit for research on pre-implantation embryos is generally accepted because beforehand there is no fetal tissue differentiation, and after 14 days it would be difficult to find an acceptable limit. Nevertheless because it is arbitrary, it may have to be re-evaluated in specific cases. (ibid.: 1048)

As a scientific society, they obviously have a strong commitment towards embryo research. But with a twofold ambition, as they clarify: to foster both, constant improvement in patient care and to provide support for pursuing fundamental research questions in the field, which are not mutually exclusive.

However, ESHRE's main approach to tackling ethical issues is principle-based. Of course, the IC as previously analyzed can likewise be considered as a regular principle, but it also constitutes a practical one, or rather the practical translation (or operationalization) of the principle of reproductive autonomy. This is particularly entwined with a so-called healthcare logic of choice as well. And ESHRE's version of principle-based argumentation can also be viewed in the light of patient choice as the dominant healthcare logic in the Western hemisphere. However, there

are some differences in how patients are conceptualized in the two cases at hand, but I will return to these aspects in more detail in the next chapter (7).
Now, I would like to draw attention to the two principles of *'reproductive autonomy'* and *'the welfare of the child'*, which are situated in a broader justificatory narrative that constitutes the specificity of (in)fertility treatments in general. The ESHRE TF for ethics and law specifies these principles as the *'double responsibility'* of the fertility doctor that has profound implications for the entire moral fabric of ART and its treatment relationships:

> Fertility treatment is special in that it is not just concerned with solving or managing a medical problem in the patient, but aims at the birth of a healthy child. This has **implications for the moral fabric of the fertility treatment relationship:** the interests of the future child should be taken into account not only by the couple requesting medical help, but also by the doctor whose help is being requested. As stated in this Task Force's earlier document on 'The welfare of the child in medically-assisted reproduction', the fertility doctor's causal and intentional contribution to the parental project makes him/her **co-responsible** for the welfare of the future child. **Fertility doctors**, therefore, **have a double responsibility: to the patient and the child.** (ESHRE TF 17, 2010, 3; emphasis added)

Here, a common tension arises exactly between the two fundamental principles that characterize this field of discourse**:** *the welfare of the child* **vs.** *the reproductive autonomy of the patients*. These two basic principles are often captured by ESHRE in their sections about *'general principles'*, where *'reproductive autonomy'* constitutes one quite dominant principle. Whereas *'the welfare (interests) of the child'* is primarily encapsulated in the two principles of *'beneficence'* and *'non-maleficence',* both of which are simultaneously referring to the patients' rights (or also donors in third-party reproduction) as well as the welfare of the future child. Both must always be taken into account and weighed against each other, and in the case of ESHRE, the welfare of the unborn child is a key principle in their evaluation of ART practices. These two principles are related by ESHRE in the following way:

> At stake are two main principles. Firstly, the technology [PGD] is justified by referring to the **welfare of the child** by **avoiding harm** to the future offspring. Secondly, the application of PGD increases the **autonomy of the parents**, both by allowing them to choose a technique that better fits their moral principles and reduces the psychological burden (by avoiding repeated terminations of pregnancy) and by giving them the possibility to protect their interest in favouring the health of their offspring. (ESHRE TF 5, 2003: 650; emphasis added)

This statement is taken from an ethical opinion statement on *pre-implantation genetic diagnosis*, which is a technology (specifically, a laboratory procedure) for the genetic screening of IVF embryos in order to reduce various risks of passing on inherited conditions. In this paper, they deal with this kind of question under the header of "fundamental ethical principles". The basic method of the principle-based approach is to balance them against each other. In the quote above, this is argumentatively realized in the form of actually combining the two principles by stating that, through the use of this technology, both the potential harm to future offspring can be avoided (or at least reduced) and the autonomy of the intended parents as patients can be simultaneously increased. This also stresses that the intended parents should have a strong interest in encouraging the wellbeing (which means health) of their offspring by using this technology.

ESHRE puts a strong and primary emphasis on the principle of the welfare of the child, which is basically negotiated under the non-maleficence principle. This does not focus exclusively on this party – even though it is one central (anticipated) party in ART – but also refers to other potential third parties in the ART process, including donors. This rather strong emphasis on the welfare of the child can be seen as a special feature of their principle-based approach, in contrast to the ethics group of ASRM. If these principles are met, i.e., adequately considered and weighed by medical professionals, then they serve as a legitimation for the use of this technology, and specifically when the welfare of the child is not at risk.
Another TF ethics and law document on the issue of *multiple pregnancies in ART* states in a section called "general ethical principles":

> All the principles outlined are taken into the context of our **joint parental and professional responsibility towards the future child(ren)**. A recurrent theme in all matters of assisted reproduction, it is especially important when the facts show that some techniques do put the future child, a vulnerable future party, at high proven risk (see Introduction). (ESHRE TF 6, 2003: 1977; emphasis added)

Here, they introduce a further layer by emphasizing that all these principles are underlain not just by a claim of empowerment and patient autonomy, but also by particular forms of responsibilities on both sides – parents/patients and professionals – when it comes to the involvement of vulnerable groups, such as 'future children'. But as already said in other contexts, it could be the donors, who are considered the vulnerable group because, for a long time, they were not properly considered in many biomedical reflections. So it is this shared responsibility, which also creates its own tension, that is one reason why the informed consent (adequate, evidence-based information) is seen as such an important device for resolving these issues of responsibility in ART. By shifting much of the responsibility to the individual sphere.
Or, in the case of *posthumous reproduction,* they explicitly draw attention to a further dimension regarding the autonomy principle:

> The principle of **respect for autonomy** means generally that we have to respect people's decisions. However, this **does not imply unconditional acceptance** of the patient's wishes. **Two limitations are relevant for the moral evaluation**. First, real respect for autonomy implies the creation of conditions that promote well-considered decisions reflecting the person' s value structure. Second, the prospective parents should take into account the effect of their wishes on the future child. (ESHRE TF 11, 2006: 3051; emphasis added)

In their understanding, autonomy is obviously not something that applies unconditionally, because it relates to liberty. Liberty can be limited on reasonable grounds, such as when liberty causes interference with the autonomy of others (third parties, but see more to that aspect in chapter 7.3). Their concept of autonomy is apparently always associated with the interest(s) of the future child and thus, is anything but a simple endeavor. This is because it is not just about an unlimited and unconditional acceptance of people's decisions, but rather includes a range of duties and responsibilities that have to be taken into account as well.
In this cited section, they also mention this highly interesting aspect of "creating the conditions of promoting well-considered decisions", which, in the context of ART, entails that professionals (clinics and centers) have to take care to create such an environment that allows people to make such well-considered (i.e. responsible and dutiful) decisions. Therefore, they declare how

the autonomy principle should be achieved in practice: “The moral and legal recognition of autonomy is achieved by obtaining the informed consent of the patient” (ESHRE TF 7, 2004: 461). It is again the informed consent as the moral and practical translation of patient choice, which operates as a main, and thus regular, mode of justification in their ethical evaluation.
They further point out that the obtainment of IC is tied to the condition of the ‘decision-making capacity’ (‘competence’) of a person, which for instance, differs between adults and children. Children are introduced since disease could also affect their reproductive potential, which could make measures to preserve their fertility necessary as well. Thus, they declare: “There is no need to fix a specific age at which an adolescent becomes competent to make these decisions. In fact, it is more appropriate to speak of emerging autonomy rather than of a specific age to consent” (ibid.). This example of children and their decision-making competence also points to something even more essential in the context of autonomous decision-making, namely that information needs be understood and not only provided (even if this is done in an all-encompassing way through an IC form). The necessary prerequisite for decision-making (patient choice) constitutes an adequate understanding of the information provided, so the provision of information alone is not sufficient. That means, autonomous decision-making is not just tied to the decision-making competence of a person, but also to their adequate understanding. This definitely would fall within the remit of professionals to ensure that information is understood, otherwise genuine autonomous decisions are made impossible.
In comparison, the ethics committee of ASRM produced a similar paper on *posthumous reproduction* (i.e. posthumous gamete retrieval), where they explain the conflict between the interests of future children and prospective parents (patient choice argument) in the following way:

> Another concern is for the child, who would have only one parent and who might have been conceived under difficult circumstances (9). Some critics might argue that posthumous assisted reproduction violates the autonomy of the subsequent child. However, because the child would not have existed without the procedure, the concern cannot be that the child's choices were not respected in the decision to employ it. Rather, the concern is that the child might be raised in a situation that is difficult for him or her. (…) Or, the child might be saddened or otherwise psychologically affected by the knowledge that one parent died before birth. Without assisted reproduction, however, the child would not have existed at all; so one way to view these arguments is that they must show that the child's life circumstances are so unfortunate that it would have been better never to have been born. (ASRM, 2018: 3)

As one can clearly notice from this statement, the ASRM ethics committee does not really operate or include the concept of ‘the welfare of the child’ into their concept of autonomy, which indeed indicates a stark difference. Rather, they reject the argument of the autonomy principle on the side of unborn children, because, in their view, “the concern cannot be that the child's choices were not respected in the decision to employ” ART (ibid.).
This argument is, of course, not to be dismissed, but this probably constitutes the reason why ESHRE for instance speaks about the interests (or the welfare) of the future offspring (and not their autonomy) and requires that it should be respected in all steps of ART treatments. However, in the examples to follow, ASRM indeed considers the interests of the child, which means the possible consequences of this practice for the child’s future life. They emphasis the difficulty of assessing this in terms of the ‘autonomy of the child’, especially without much

experiential knowledge on psychosocial aspects for the children born under these certain circumstances.

And yet, the 'welfare of the child' as a principle does not play an important role in their ethical assessment regarding the admissibility of this medical procedure. It is the very category of 'future/potentiality' which they reject as a legitimate argument, instead they argue that the contrary has to be shown that "the child's life circumstances are so unfortunate that it would have been better never to have been born" (ibid.). This argument seems somehow difficult, or illogical even, in their argumentation, because if you cannot anticipate the choices (or rather, the interests/wellbeing) of a future child, it is likewise difficult to assess the child's future life circumstances from a present.[90] And just because something presents itself from today's perspective as something that could develop in a certain way does not necessarily mean that it will do so, because things can always turn out quite differently.

In another paper on *nonmedical sex selection of embryos*, ASRM clearly locates the responsibility of providing this procedure on the side of the providers (i.e. the medical professionals). In their point of view, a clinic or center must decide to provide or not to provide this practice, and, if they do so, then they have to create an environment where patients are able to make informed decisions (including having written policies under which conditions they provide it). They also emphasize the controversial nature of this technology, noting that:

> Arguments regarding patient autonomy and reproductive liberty have been offered in support of the practice [nonmedical sex selection]. Risks and burdens of the procedure, gender bias, sex stereotyping and nonacceptance of offspring, efforts to guard against coercion, and issues of justice all raise concerns about the practice. Practitioners must take care to ensure that parents are fully informed about the risks and burdens of the procedure and that they are not being coerced to undergo it. Because the practice is so controversial, clinics are encouraged to draft and make available written policies setting forth whether and under what circumstances nonmedical sex selection will be available. (ASRM, 2015: 1421)

This again constitutes a clear moment of promoting the self-regulatory capacity of the profession. Of course, throughout the paper, they spell out potential conditions under which it would be deemed unethical from their organizational point of view to provide this practice, and under which settings it could be ethically acceptable. Although, they provide their authoritative suggestions, they ultimately leave it up to the discretion and responsibility of the provider to make their own written policies on how to deal with this in practice. This is an interesting instance of how to deal with the question of responsibility when it comes to new technological treatment possibilities that are conceived as potentially controversial – sometimes still experimental when it comes to application – within the profession, but also in society more generally.

Here we clearly see the differences between the two justificatory approaches: ESHRE rather tries to go through the individual aspects and principles in more detail, whereas ASRM argues for a much more practice-oriented approach (sometimes also more generally) by only gesturing

[90] Anyways, the notion of choice is crucial in this context and deserves separate consideration, to which I will return in chapter 7. The concept of choice constitutes a main node in analyzing this particular justificatory work that is done here.

towards these aspects but without going into fine detail. Because they rather see it as the responsibility and task of practitioners to position themselves if there is room left for it, and they think that they do so when proposing the IC or written policies as the adequate tool to cope with these – partly unsolved – questions. This does not necessarily mean that they do not reach the same, or at least similar, conclusions, in their own way.

For instance, in the example above, both committees did not reach a unanimous position because of the varied legal and moral backgrounds of the practice of non-medical sex-selection. Because both could not reach a consensus, the ASRM leaves the issue to the discretion of practitioners, but recommends the development of clear written policies (a framework so to speak) that should set out the conditions for engaging or not engaging in this practice (ASRM); while ESHRE highlights the legal context (pointing to existing bans of this practice in European countries) that must be the reference point for practitioners in this regard. Specifically, they state:

> (…) [legal] clarification is needed as to whether it applies to fulfilling parental requests for additional selection in the context of a medically indicated IVF/PGD (or PGS) procedure. Depending on the precise wording of the ban in different countries, additional selection (…) may or may not be against the letter of the law. Professionals need to know what the legal position is with regard to answering such requests. ESHRE TF 20, 2013: 6)

ESHRE considers these issues much more principle-based, and even delves into a discussion on the entangled nature of the medical and non-medical, linguistic subtleties and respective discursive formations. For instance, when considering *cryopreservation*, they start their 'general principles' section with a discussion around the 'beneficence' principle (doing good), which belongs to the Hippocratic core of medical ethics, which "(…) traditionally related to an account of the good in medicine understood as preventing and curing disease (and caring for the ill)" (ESHRE TF 18, 2012: 2). As they further spell out, reproductive medicine is widely regarded as fitting in this medical model, although it is not strictly about curing or restoring natural fertility, but rather overcoming it by avoiding the consequence (involuntary childlessness).

This is a case where they enter into a more philosophical discussion about the principle of beneficence, in the sense that they reason where these arguments come from:

> The second, more fundamental, argument is that the appeal to the limits of medicine wrongly suggests that notions of health and disease can simply be inferred from facts about biological functioning without reference to socially mediated understandings (Richman, 2004). That this is not the case is quite obvious from the intractable nature of debates about whether and under what conditions infertility should be regarded as an instance of ill health. (ibid.: 2)

This is an interesting instance of their principle-based argumentation, which clearly sets their argumentative justificatory work apart from that done by ASRM, because ASRM for their part would never enter this kind of discussion. Not only do different types of evidence, which is indeed a decisive factor in their assessment, lead to a revision of their position (here in the case of cryopreservation for non-medical reasons). But it is the very contextualization of these treatments within a particular understanding of a Western healthcare model, especially in

relation to what actually health and illness means in this understanding. Foucault, for example, traced the mediation or intertwinement of the social and biological in medicine and the humanities, as follows:

> If the science of man appeared as an extension of the science of life, it is because it was medically, as well as biologically, based: by transference, importation, and, often, metaphor, the science of man no doubt used concepts formed by biologists; but the very subjects that it devoted itself to (man, his behaviour, his individual and social realizations) therefore opened up a field that was divided up according to the principles of the normal and the pathological. Hence the unique character of the science of man, which cannot be detached from the negative aspects in which it first appeared, but which is also linked with the positive role that it implicitly occupies as norm. (Foucault, 1973: 36)

Hence, it is precisely this co-production to which ESHRE's ethicists refer when they emphasize the entangled nature of biological functioning and socially mediated understandings that leads to our conceptions of health and disease.

The TF much more often enters into an exchange with what was previously called public debate and empirical bioethics (chapter 4), including increasingly social science-based approaches, albeit in a quite reduced form and understanding. While it might be plausible (or easier) that a specific kind of scientific evidence justifies a widespread implementation of a new technology for 'medical' indicated fertility preservation, in terms of safety measures and effectiveness, it is not likewise straightforward that it does so for so-called 'social' or 'non-medical reasons'.[91] However, in the very same paper, they refer to another kind of empirical evidence and terminology:

> In the quoted study on **a group of potential users**, **women referred to reproductive safety as a determining factor in their decision-making** about fertility preservation" (Stoop et al., 2011b) (…). Although the number of children born from cryopreserved oocytes is still small, there is no indication that they would be at increased risk of adverse health outcomes. But **more data are clearly needed**. These should not only be based on short-term, but also on medium- and long-term **follow-up** of children. Centres offering this novel technology have a **responsibility to contribute to the collection of these data**. (ibid.: 3; emphasis added)

Obviously, they also have started to explicitly include additional dimensions, such as social aspects, including studies on *'user'* expectations and attitudes, but also underpinning their positions with empirical evidences (i.e. justifying and not just stating their principled conclusions and recommendations).

This observation is very much in line with what Borry and colleagues already noticed in 2005 about the changing relationship between ethics as a core discipline and social sciences as empirical auxiliaries, what they also labelled as *a transition from laborious to laboratory dialogue*:

> Scholars now suggest that the use of sociological, anthropological, epidemiological, and psychological methods to study ethical issue has emerged as a novel form of scholarship in bioethics, that a 'new form of

[91] Or as ASRM would put it: "The critical difference between the oocyte cryopreservation examined in this Opinion and that which is done when gonadotoxic therapy is imminent is its non-emergency nature. It is being undertaken as a matter of planning before a medical indication has materialized and will be referred to as ''planned oocyte cryopreservation'' or ''planned OC.'' (ASRM, 2018: 1023). However, to these terminological subtleties I return to in Chapter 7, when considering the role of these Ethics Committees when it comes to issue-making and -framing.

> ethics paper' has appeared, and that bioethicists'' interest in empirical data continues to grow. (Borry et al., 2005: 62)

The appearance of a new form of ethics paper can be recognized in these cases as well, but not just in how far empirical evidence becomes superior in these opinion papers. This is also evident by the increasing use of different (empirical) methods and terminologies, for example, when suddenly the discussion is about potential users and not patients, or when they start to consider their interests not just in principled terms but in the form of engaging with research about attitudes towards fertility preservation and reproductive safety.
It is noticeable that they use the term potential users here instead of talking about patients, women or couples, as it would have been the case in earlier statements. This indicates an issue modification: the new technology (cryopreservation with vitrification technology in this example) necessitates a shift in their ethical assessment methodology, because it changes the expectations too, which in turn is an interesting example of how issues around ART are actively made, modified, and, indeed, co-produced in these ethics papers.
The use of the notion of 'the user' is interesting because it initially emerged rather out of an IT-context, so from computer science. It frequently becomes used in social science research as well. It is remarkable enough that the notion is so prominently applied in the social sciences, but even more remarkable that it gets used in the context of ART treatments and bioethics.[92] At first glance, it may seem slightly odd to use this notion in the context of ART, but it is precisely the context of technology application and implementation that encourages the use of this terminology.

What is further apparent is that the principles of *(reproductive) autonomy, beneficence, non-maleficence and justice* are quite malleable when moved from an individual level to a societal level. An example of this is when individual considerations, such as the question of what a 'good life' means for an individual person, changes into issues of clinical, and thus societal, cost-effectiveness. However, the TF more or less excludes the question of 'good life' from its discussion, because:

> In a secular debate, the problem with arguing from views about 'the good life' is that they rest on religious or naturalistic presuppositions that not all participants necessarily share. As imposing such views on others is morally unacceptable, fertility specialists should leave it to the women themselves to make their own informed decisions about the need for fertility preservation. (…) A paternalistic attitude from the physician should be rejected. That a fertility centre may still decide not to start treatment for reasons of cost-effectiveness and scarcity of resources is a different matter. (ESHRE TF 18, 2012: 3; emphasis added)

[92] Of course, one has to look carefully how this notion comes to be used, so in which particular contexts. If, for instance, a social science project is about 'computer' usages (digitalization, media use etc.) in the broadest sense, then it makes somehow sense; whereas when it is used increasingly in other contexts as well, i.e. if it starts to migrate into completely different constellations, a social scientist has to raise at least the question what does this transformation in terminology means. What does it mean if we imagine people as (potential) users (here in case of (in)fertility treatments, or e.g. more generally, in context of healthcare)? Such terminology is always joined by particular assumptions and claims which of course can be questioned.

This includes, according to the TF, the choice of whether to have children, with whom, how many to have and, respectively, when to reproduce. Hence, the prioritization in one's personal life is in line with the principle of reproductive autonomy and cannot be decided by others for others. Under the rubric of justice, they span a wide range of issues, from reproductive justice underpinned by feminist claims (which can be fulfilled technologically with options like fertility preservation) to broader societal issues of cost-effectiveness (e.g. avoidance of oocyte donation), which rather follows an economic (capitalist) logic, and/or societal benefits, such as increasing birth rates in developed countries.

However, there are other perspectives that can be considered, too. For example, disability activists have claimed that individualizing decisions potentially obscures the initial intention by creating exactly the reverse, by putting moral pressure on the individual to use the available interventions and options. Additionally, one can seriously ask if this does not actually constitutes a move to shift responsibilities in the name of 'autonomy' from the professional sphere (so clinical decisions) into the patient's sphere, which could lead to an overload on the patient's side at the end of the day, because many issues simply cannot be resolved at the individual level.

Something similar happens with the use of feminist arguments, and actually also with the arguments from social sciences as well. The core question here is: what remains invisible in this particular technical framing of ethical assessment around issues in ART? This demonstrates the accuracy of what Evan's has claimed in his sociological studies on bioethics regarding the character of these principles: by applying a small set of principles, they become an expression of a quite rationalised way of discourse, which constitutes a system of commensuration and thus, reductionism (Evans, 2000). This small set of principles makes sense because they emerged first of all within the US legislative context, where a simple decision-making system was preferable and needed. That means that it is not an accident that these principles got robustly institutionalised within a governmental environment by transforming them into legal norms.

It is interesting that ESHRE, as a quasi-European organisation, operates much more strongly – at least more explicitly – with this principles-based model than its US-counterpart ASRM does, given its early US-origins. However, this only speaks to the extent to which the regularity of a certain discursive practice is at work – in its singular and structural functioning.

Even though the principle of 'the welfare of the child' is much more at the centre of their ethical deliberations (rather than exclusively patient autonomy in the form of the IC), they are nevertheless governed by the same discursive rules of speaking, which means that in this particular discursive practice the issues and objects are organized around these same principles (alongside empirical evidences as justification and other procedural modes that I have analyzed in the beginning of chapter 6). These principles, including the IC form as operationalization of the autonomy principle, are the main modes of justification provided in this discursive formation of bioethics.

6.4 Résumé

The particular combination of bioethical principles and empirical evidences reflects very much the intention of the inventors of this principle-based approach – Beauchamp and Childress – to unite the common morality with the method of reflective equilibrium, because "this strategy allows us to rely on the authority of the norms in the common morality, while incorporating tools to refine and correct unclarities and to allow for additional specification of the principles" (Beauchamp & Childress, 2013: 387). Interestingly, empirical evidence has become one of these dominant tools in bioethical reflection to refine, correct, strengthen, specify, and justify these very principles, including the informed consent. *Common* to both ethics committees is this strong commitment towards evidence-based arguments, i.e. underpinning or combining the other two modes with evidence-based justifications.

One main *difference* between the two ethics committees should be highlighted and summarized at this point, because it is relevant for the further course of analysis: While ESHRE puts quite a strong emphasis on the welfare and interests of the future child, ASRM is much more concerned with the interests and rights of the patients, thus reproductive autonomy/liberty, but in form of the IC. This becomes reflected in two different ways: *First*, it becomes visible through their argumentation as we have seen (i.e. the modes of justification they use and in which ways) but it is also visible when they point to the same discursive rules. As I have tried to demonstrate throughout this chapter, ASRM puts a clear emphasis on the informed consent process as a discursive argument, with the principle of 'reproductive autonomy/liberty' at its core. This results in a clear focus on the rights of the patient.

ESHRE, on the other hand, argues more in the tradition of a so-called 'principalist' method, i.e. they concentrate on balancing the four biomedical principles, but with particular attention to the best interests of the future child.

The *second* or other way in which this difference gains visibility is through the naming of the organizations themselves: On the one hand, we have a European organization with the name: "Human Reproduction and Embryology", which implies a clear focus on "embryology", from which can be concluded that reproductive biology and the embryo as the scientific basis of IVF and ART is a rather prominent concern, but also the future child. The North American organization, on the other hand, as the name suggests, is dedicated to "reproductive medicine", from which one can conclude that there is a particular focus on patients, their reproductive problems, treatments and consequently their patients' rights.

Of course, both scientific societies are dedicated to (medically assisted) reproductive medicine and related issues in general, but the different naming already indicates a strategic thrust. Certainly, it makes a difference whether the notion of 'embryology' (ESHRE) is included in the name of an organization, or not, or if it is 'reproductive medicine' (ASRM), instead of 'human reproduction' (ESHRE).

In any case, all three argumentative modes of justification tend to propose quite technical frameworks for the ethical evaluation of issues in the field of ART. Despite the fact that many of them constitute actually value-based questions and not merely knowledge questions that can be decided on the basis of scientific evidence. The different combination of argumentative

justifications, however, could be seen as a response and an attempt to handle the different levels of value and knowledge questions and their complex entanglements. In this sense, different justificatory arguments need to be mobilised, as these different levels of value and knowledge dimensions need to be addressed. However, there is a strong tendency to objectify (ergo rationalize) these discussions, which means to underpin principle-based arguments with scientific evidence as the decisive judgement category in these considerations.

Although, the two modes of justification, biomedical principles and informed consent, already have the tendency to prioritize a technical frame of ethics (scientific aspects), which means prioritizing the feasibility dimension of a procedure or technology, rather than its social aspects, or societal desirability. From the moment they start to focus intensively on scientific evidence as an argumentative resource, this prioritization becomes even reinforced even more by negotiating almost every question under a technical frame and thus, transforming it into a (more or less pure) knowledge question (Bogner, 2021). This means, turning these questions very much into mere questions of feasibility, in terms of, safety considerations, for example. When this happens, the second question reduces 'merely' to how this can be translated into various practice contexts (clinics, doctor's practice, or into a broader regulatory environment across different countries…). I deliberately put the word 'merely' in quotation marks because also 'the how' to implement and regulate a new technology or procedure, also in regulatory terms, is not a trivial question, either. Both are constituting a *socio*-technical as well as political process, which often proves quite a challenge.

Yet, the question of if a new intervention should actually be further pursued is a quite different one altogether. Both types of questions: those about ends and those about means or implementation are completely different, requiring different modes of engagement and different types of language(s). As Evans already pointed out: the discussion in bioethics is not so much about so-called ends but rather about means, with which he criticizes a kind of thinning out of democratic debate with the main consequence of making impossible a more radical critique, or questioning of technology itself (Ashcroft, 2004). What such a radical critique might look like and who would be responsible for its formulation, however, remains open. In any case, it is crucial to involve diverse publics in these debates and open them for clarifying the various – and sometimes hidden – value questions. Or as Sarah Franklin put it: "these are the real "facts of life" we need to understand, and as always, they are more complicated than they seem" (Franklin, 2019).[93] However, I hope that the analysis and mapping of the factually accepted standards and rules of successful argumentative justifications (and also reasonings) that my analytical work provides is a prerequisite for demands regarding their improvement (Ott, 2021), or even change and critique.

With Foucault, one could also speak of the specific field of *statements* that I have tried to map through and with the analytic lens on justifications – the modes of justification represent a specification (singularization) of this particular field of statements in this bioethical discursive formation. Further, this work of justification must be understood in the situated context from which it emerges. Both committees are embedded in a specific but perhaps comparable

[93] https://www.nature.com/articles/d41586-019-03270-4 (accessed on 6th June 2023).

institutional environment, but there are also differences in terms of the socio-cultural and geo-political contexts, too. It is still important to note that these argumentative modes of justification are often insufficient to capture all the different dimensions of ethical questions, or that they often distract from the underlying issues. Or, to put it differently, sometimes they provide clear answers to the 'wrong' questions, because these modes only allow to pose particular kinds of questions, which I will also try to show in the next chapter. The discourse, the invisible order which, like a secret economy, binds the space of possible truths in a time on fixed trajectories, results from the distribution pattern of the statements themselves (Foucault, 1972; Gehring, 2004).

Chapter 7: Strategic dynamics and ruptures in the bioethics discourse: Bioethical issue-making in the context of wider healthcare logic(s)

In the previous chapter, the focus was basically directed at detailing and analyzing the justificatory work done by the two ethics committees of the ESHRE and ASRM. I was particularly interested in the specific configuration of the three argumentative modes of justification: *scientific evidence,* the *informed consent (IC)* procedure*,* and the four-*principle-based* approach that they repeatedly put forward and construed in their bioethical opinion statements (but also at conference meetings and in discussions) for the ethical acceptability of practices in assisted reproductive medicine.

The aim now is to show how the very issues and objects of assisted reproductive medicine are constructed around these particular modes of justification, and how they are grouped, produced, transformed, combined, or perhaps even disassembled and/or reassembled – or, to use Asdal and Hobæk's words, modified (Asdal & Hobæk, 2020). What, then, are the linking logics, main themes, and strategic elements that permeate this particular field of statements? And how are they condensed into the form of a very specific bioethics discourse? At this point, it is worth explicitly restating the importance of the Foucauldian understanding of a *statement* and the idea that it constitutes the elementary unit of a discourse:

> (…)it [the statement] is endowed with a certain modifiable heaviness, a weight relative to the field in which it is placed, a constancy that allows of various uses, a temporal permanence that does not have the inertia of a mere trace or mark, and which does not sleep on its own past. Whereas an enunciation may be *begun again* or *re-evoked*, and a (linguistic or logical) form may be *reactualized*, the statement may be *repeated* – but always in strict conditions. (Foucault, 1972: 105)[94]

As we have seen, these modes of justification operate in the written ethical statements as powerful tools that serve to justify practices in reproductive medicine and ART as either ethically acceptable practice, or sometimes – in rather rare cases – as (temporarily) unacceptable.[95]

In this chapter, I now focus on the various co-productive dynamics and strategic ruptures involved in the issue-making of this bioethical decision-making work. For this reason, I analyze in which ways the two healthcare logics play out in the committees' justificatory work; these two healthcare logics were first scrutinized and described by Annemarie Mol in her book *"The logic of care. Health and the problem of patient choice"* (Mol, 2008). To do so, I focus specifically on the *logic of choice* as the characteristic – and I would say implicit – logic of the organization of Western healthcare systems. Since the decision-making work and justificatory arguments of

[94] "(…) ist sie [die Aussage] mit einer bestimmten modifizierbaren Schwere, mit einem Gewicht ausgestattet, das in Beziehung zu dem Feld steht, in dem sie sich befindet, mit einer Beständigkeit ausgestattet, die verschiedene Verwendungsweisen erlaubt, mit einer zeitlichen Permanenz, die nicht die Tatenlosigkeit einer einfachen Spur hat und nicht auf ihrer eigenen Vergangenheit schlummert. Während die Äußerung *erneut begonnen* oder *erneut evoziert* werden kann, während eine (sprachliche oder logische) Form *erneut aktualisiert* werden kann, hat die Aussage als Eigenheit, *wiederholt* werden zu können: aber immer unter ganz strengen Bedingungen" (Foucault, 1973: 153; deutsche Übersetzung).

[95] Whereas these ethics committees would formulate it in a much more moderate form, as e.g., too risky, or in case they could not reach an unanimous position, they would state that clinics or provider should issue written policies under which conditions they would provide an application or not, etc..

these ethics committees are not produced in a communicative vacuum, I am orienting myself with the perspective of how these different argumentative modes of justification are co-produced with this particular (*implicit) logic of choice* in healthcare. In this regard, and with Foucault in mind, one could also potentially speak of a *historical a priori*, which at first glance appears as an unusual expression or combination, but which is an essential empirical figure (rather than a formal one) in his work:

> Juxtaposed these two words produce a rather startling effect; what I mean by the term is an *a priori* that is not a condition of validity for judgements, but a condition of reality for statements. (…) The reason for using this rather barbarous term is that this *a priori* must take account of statements in their dispersion, in all the flaws opened up by their non-coherence, in their overlapping and mutual replacement, in their simultaneity, which is not unifiable, and in their succession, which is not deductible; in short, it has to take account of the fact that discourse has not only a meaning or a truth, but a history, and a specific history that does not refer it back to the laws of an alien development. (Foucault, 1972: 127)

So, this *a priori* does not escape *historicity*: it does not form an atemporal structure; instead, it is defined as the group of rules that characterize a discursive practice, but these rules are not imposed externally on the elements that they relate to. Instead, they are implicated in the very things that they connect and if they are not modified with the least of them, they modify them and are transformed with them at certain crucial thresholds. The historical *a priori* of the positivities is not only the system of a temporal dispersion; it is itself a transformable group because it is historical and not formal (ibid.). By the historical *a priori* as well as the notion of 'positivity' he describes the threshold of autonomy that a system of statements reaches – that is, an ensemble of statements that perpetuates itself – which is no longer merely an accumulation of unrelated utterances. This I will combine with an analysis of the healthcare logic(s) – especially a logic of choice –, which gives me an additional but connecting framework to analyze the *linking logic* in this bioethics discourse and, thus, the relevant value positions that come along with such a logic and its particular justificatory work:

> I am after the rationality, or rather the rationale, of the practices I am studying. Here the term 'logic' helps. (…) It invites the exploration of what is appropriate or logical to do in some site or situation, and what is not. It seeks a local, fragile and yet pertinent coherence. This coherence is not necessarily obvious to the people involved. It need not even be verbally available to them. It may be implicit: embedded in practices, buildings, habits and machines. (Mol, 2008: 9)

So do these practices of bioethical engagements and decision-making. There are many sites of knowledge construction in (bio)medicine. Mol, for example, has applied the question from earlier science studies to the medical context of hospitals by asking: how is reality enacted in a hospital and is part of a particular practice? In doing so, she has shifted her gaze from earlier laboratory studies as spaces where interventions are transformed into representations to the hospital as a space where representations are in turn transformed into interventions (two sides that are closely intertwined in the forms of biomedical knowledge production). I then turn my gaze to an entirely different space of biomedicine: the (written) ethical justificatory work done by two specific ethics committees, where I focus on the (re-)articulation of these modes of justification and the healthcare *logic of choice*. In this chapter, I make an attempt to show that there are a number of other spaces besides clinics where this particular logic of choice becomes

functional, namely in the discourse and the justificatory work of these bioethics committees. I argue that ethical opinion statements should be considered as crucial spaces in which biomedical issues, especially those of a controversial nature, are negotiated and, basically, are made. It is also here where the very *moral fabric* of human reproduction becomes *enacted* through naming, classifying, framing and shaping, defining and boundary drawing, in short, *the making of issues*.

Against this backdrop, I look at how these specific modes of justification come into being in these bioethics papers, i.e. how they are re-articulated with the healthcare logic of choice in particular. In chapter 7.1*,* I elaborate on an increasing trend of 'scientification' that has been seen in recent years in both bioethical debates in general and specifically those around reproductive technologies. Through this, I capture questions of issue-making and how this is done in and through these statements alongside two concrete examples. A further chapter 7.2 ponders the modifying work of these ethical papers with regard to different healthcare contexts, such as public health and individual patient care. Here, I examine how individuals and collectives are linked together in such bioethical discussions and what this means in the context of the provision of fertility treatments. In chapter 7.3, I revisit the *'problem' of patient choice* and how care might be articulated when it comes to bioethics. This involves the question of how, in the context of patient autonomy discussions, *care* is imagined in these written statements – if at all; and how and where questions of responsibility become distributed and located. The final chapter 7.4 addresses more explicitly the question of governance and self-regulation when it comes to this particular biomedical community and the role of these ethics papers therein. This governance question refers to the functions and roles of these scientific societies within a particular geopolitical and regulatory context in which they are embedded.
I also re-emphasize the role and importance of their written bioethical work in making (in)fertility a governable issue. This chapter is then specifically about how the ethics committees see and articulate their self-perceived role when it comes to expectations and notions of governing this field of reproductive technology. These questions are closely related to the certain kind of justificatory work they perform in these statements, which in turn is indicative of their specific imaginations of a self-regulating medical community.

7.1 Bioethical issue-making: A process of 'scientification'?

Based on an increasing use of scientific evidence as the main rationale and justificatory argument, a process of 'scientification' commences to shape issues and organize their conceptualization in significant ways, namely the way how one tends to think, talk, and judge about them. But this does not yet tell us what it means how – in which exact ways – this increasingly scientized or epistemologized discourse forms its objects, concepts, and issues:

> An issue is also the 'thing'. Analysing issue politics then needs to take all these three dimensions into account and consideration: how and to what extent an issue is 'broken open' before reaching a closure and decision, the very procedural elements through which this happens, and how this is combined (or develops in tension) with acquiring knowledge of the very 'thing' or issue in question. (Asdal & Hobæk, 2020: 264)

Issue-making is a striking effort that is performed by both ethics committees through their written justificatory work. In the following chapter, therefore, I try to show what this means and how it gets visible through the material: their ethical opinion papers. The documents are integral to the very issue at stake and do not merely represent some reality beyond and outside the text (Asdal & Reinertsen, 2022). In the bioethical opinions of the two ethics committees, we can witness in what dominant ways a *logic of choice* permeates and shapes the very conceptualization of the actual issues and questions.

To begin with, I want to clarify how issue-making hangs together with the fact of how they actually come to talk and write about a certain 'thing', or other matters of concern. The decision to actually discuss a particular medical procedure or reproductive technology is influenced by a number of different factors: societal concerns expressed in public media and debates, the extent and perception of controversy surrounding a technology or new treatment option, concerns of the medical profession and specific dilemmas (often classified as ethically controversial), and problems encountered by physicians in their daily practice. These are critical voices that seem important for their choice of when to consider a particular topic, practice, or technology. This means that the ethics committees do not decide on their own that a particular matter may be important but rather are guided by the concerns and interests of the community and society. This constitutes in its own right an interesting aspect and gives them a special role – a kind of moderator role –, which consists of considering certain aspects in the practice of ART in a systematic way.

How they come to decide on a subject is one thing, but an altogether different one is how they make or enact a particular issue in and through their documents with the help of different arguments and justifications. Identification through opening up and closing down, classifying, and (re)framing an issue – all this is done mainly through their justificatory arguments and by drawing conclusions that then justify their recommendations. Their distinctive lens is indeed characterized by making a considerable effort to establish a sort of metaethical reasoning, which increasingly becomes based on scientific evidence as a prime argumentative resource in their decision-making.

Sheila Jasanoff already pointed out in the 1990s the increasingly important role of science in a global policy context, which is equally reflected in these ethical statements. Jasanoff's succinct conclusions from the 1990s provide an ideal entry point for describing the background against which these written ethical statements can be read:

> With the growing saliency of issues such as hunger, disease, environmental decay, and international security, the world community appears increasingly to have pinned its hopes for the future on the accumulation of technical information. Experts play an ever more influential role in defining and controlling fundamental social problems. Not only are their knowledge and know-how deemed essential for managing our most pressing problems, but science, because of its claims to value-neutrality, seems to provide the only forum where nations can set aside their differences in favour of a common, rationalistic approach to problem solving. To "scientize" an issue is at once to assert that there are systematic, discoverable methods for coping with it and to suggest that these approaches can be worked out independently of national or sectarian interests. Science represents for many the only universal discourse available in a multiply fragmented world. (Jasanoff, 1996: 173)

When science is assigned a central role in various types of decision-making processes (policy, medical domains and others), an important implication is that science, in turn, becomes an ethical business (Pickersgill, 2012) and, consequently, ethics becomes something that is highly scientized, that is, rationalized. This becomes reflected in the way of using scientific evidence as the major justificatory resource in these ethics statements. As a result, one might speculate whether the epistemologies of science and ethics are themselves changing, or rather are in the process of transforming themselves through their re-articulation in profound and co-productive dynamics.[96]

7.1.1 The co-production of scientific evidence and morality: Making ART accessible for transgender care and the construction of what a 'good' family means

What is actually the problem with arguing and justifying medical practices and reproductive technologies as ethically defensible primarily on the basis of scientific evidence? This is the question that I pursue in this section and I demonstrate through two examples the problematic elements that this particular mode of justification enables. For this purpose, I return to the relevant subject of *ART in transgender and homosexual people* as a first example of *effective issue-making.* In this context, both ethics committees make a strong attempt to justify the case for or against access to fertility treatments by transgender people using supposedly factual evidence.

The point – of course – is definitely not that they are arguing for (better) reproductive care for transgender people, but rather how they are doing so and why it could be seen as somewhat problematic. In certain cases, it can be particularly problematic to argue with scientific evidence, especially when it comes to transgender care. What both committees do, above all, is that they create "target groups", to use Mol's vocabulary (2008), namely by grouping together people with certain ascribed characteristics who have (certain) wishes and needs and for whom specific services have to be created, and vice versa. Of course, transgender persons in the medical sense certainly represent a specific patient group that must be given special consideration and care.

For example, the ESHRE ethics group questions whether these individuals, which they also refer to as *"non-standard"* situations and relationships, constitute an appropriate and supportive environment for children's developmental abilities or a harmful one that can be supported by scientific evidence (in a paper from 2014 on "Medically assisted reproduction in singles, lesbian, and gay couples, and transexual people"). The point is that this is, in itself, a very problematic thing and, consequently, a difficult justificatory move and argument. Both are problematic: the question as well as the mode of justification that leads to an answer, although it is not clear whether the 'obsession' with scientific evidence possibly generates exactly these kinds of

[96] I will not elaborate explicitly on this aspect in the following as it does not constitute the main focus of my analysis. However, it is unquestionably an important matter and question that is involved in this process of (bio)ethical decision-making in science and justificatory work, which might have profound impacts on the epistemologies themselves.

questions that reflects the desire to prove everything with empirical and scientific evidence, which then unequivocally shows us the right way.

The expression of 'non-standard' sounds somehow inappropriate, especially from a human rights perspective, which is the frame we usually use to think and speak about these issues. It sounds quite morally charged if one understands it in terms of what counts or should be seen as 'normal', in a way. However, from a medical logic, it makes some sense to call it 'non-standard' in terms of the specific care that is needed, because it is inevitably different from care in heterosexual couples and their requests in ART. Nevertheless, it signals what is considered 'normal' in this field of practice: the heterosexual couple and the concept of the nuclear family – which is by no means self-evident. The point is not that medical care necessarily differs when delivered to these different groups of people, but it is rather the question of why, in these bioethical considerations, one request is conceptualized as the 'standard' situation whereas the other as 'non-standard'. The question is further whether there are other and more appropriate and just ways of articulating, because it is always at the same time a conceptualization of how we think, talk and act upon it. Medical language should articulate in a sensitive way what is needed in a specific care and treatment context. Because what is needed is the requirement of specific medical attention and treatment, which is basically a specific form of *care*. But if one speaks of 'non-standard', certain moral ideas about what is and should be considered to be 'standard' and 'normal' are quickly and immediately associated with it.

Therefore, even in the medical field, one can easily argue that the 40-year-old white male in general, and in the case of IVF and ART the 35-year-old white female within a heterosexual relationship should not be considered as the 'benchmark' of treatment and medication. When it comes to ART in transgender persons, homosexual people, or persons with other gender identities, they are indeed constituting specific kinds of patients in the sense of requiring special medical care and attention because treatments involving them will inevitably differ from those involving heterosexual patients. For instance, in the case of homosexual couples, a donor is always needed, or when it comes to transgender persons, fertility preservation is usually an important issue, especially if a sex change surgery is planned.

These are, however, two different things: the question of providing sufficient medical care for transgender persons and the question of if they are eligible to access such treatments due to their gender identity status. The first discussion concerns precisely the category of sex, which is undoubtedly central to ART treatments, while the second issue is more problematic because it attempts to make a human rights argument (access to and provision of ART treatments regardless of gender identity) by trying to prove or support it with scientific evidence, otherwise it would not be considered proven and thus obviously acceptable. It is problematic because human rights are morally based, individual rights to freedom and autonomy to which every human being is equally entitled simply by the virtue of being human and they are universal; that means it is impossible (by definition) to prove human rights with evidence and with good reason.

In the case of ASRM, we see a somewhat different approach, which can be explained in part by the specific socio-political background in the US, particularly when it comes to issues of

discrimination in its various manifestations. The first, more general aspect we can note when looking at their papers on access to fertility treatments for transgender people (or LBTQI+ people more broadly), as already mentioned earlier, is that the ASRM ethics committee regularly replaces its ethical opinion papers. In this context, replacement means more updating (the content of the paper) than completely replacing; however, this sometimes involves a revision of earlier categorizations and descriptions, which is often accompanied by reframing an issue, even if it is not in a fundamental way.

For instance, the title of the paper formerly called: "Access to fertility treatment by gays, lesbians, and unmarried persons …" (2013), has been changed to "Access to fertility treatment irrespective of marital status, sexual orientation, or gender identity …" (2021); and another replaced paper was re-named from its previous version "Access to fertility services by transgender persons …" (2015), to "Access to fertility services by transgender and nonbinary persons…" (2021). What we can observe here is a general shift in perceiving and framing the issue(s) at hand, once in the form of the small word "irrespective" and once by including also "nonbinary persons" into their consideration and title of the paper. This replacement process certainly reflects a sensitizing academic as well as public discourse towards the LGBTQI+ community. It represents, on the one hand, a more sensitive and inclusive approach towards LBTQI+ people that now includes non-binary people as well, and, on the other hand, a shift of categorization of people's attributes.

Even though this re-naming and re-framing shows a more sensitized way of approaching these particular requests from LGBTQI+ people, it nevertheless does not change the rather problematic way of justifying and making a human rights point by referring to and proving it with scientific evidence. Again, their final conclusion, that the denial of treatment by professionals based on such categories and prejudices constitutes instances of discrimination, and is therefore ethically unjustified, is absolutely right and not the point I am trying to make here. The problem lies in the nitty-gritty, namely in trying to justify equal access to treatments with scientific evidence, because this basically undermines human rights themselves and it also has profound implications for how the issue in question is actually thought about and enacted. I would now like to demonstrate this with a comparative example from their papers. Indeed, both ethics committees refer to the same French study in this context:

> The most recent data comes from a 12-year follow-up study of 42 French children, conceived by donor insemination, born into families with a transgender man and his wife. The research concluded that the children, interviewed by three different mental health professionals, are healthy, well-adjusted, show secure attachment to their parents, and do not evidence any gender-variant behavior (30). Thus, the data available do not support the fear that being raised by a transgender parent will necessarily result in psychopathology, identity disturbance, or impairment in psychosocial functioning (9-12, 30). (ASRM, 2015: 3)

And ESHRE notes:

> The document stresses that categorically denying access to any of these groups cannot be reconciled with a human rights perspective. If there are concerns about the implications of assisted reproduction on the wellbeing on any of the persons involved, including the future child, a surrogate mother or the applicants themselves, these concerns have to be considered in the light of the available **scientific evidence**. (ESHRE TF 23, 2014: 1859; emphasis added)

And further, in the case of transgender applicants, they conclude the following:

> Unfortunately, long-term follow-up research on adult transsexuals is, again, sparse. There is some limited evidence that transsexual males show fewer psychological disturbances and less psychopathology, have more stable relationships with their (female) partner and are socially better integrated than transsexual females (Baetens, 2003). There are presently hardly any follow-up studies regarding the psychological well-being of their children. Although many transsexual people already have children, the large majority were born before their parents' transition. Preliminary findings suggest that children adapt and that there is no support for concerns that their parents' trans-sexualism directly adversely impacts on these children (Green, 1978). (…) Obviously, children conceived by transsexual people after their gender identity shift need not adapt to a new parental identity, which may well make things easier. A 12-year follow-up exploratory study including 42 children raised by transmen and their heterosexual wives after donor insemination suggests that the children are normal and happy (Chiland et al., 2013). (ESHRE TF 23, 2014: 1861)

The passage that ASRM cites to justify, using scientific evidence, that these families (as opposed to others, namely heterosexual couples) create a safe environment for children remains the same as in their previous position paper (2021). This shows that their general approach and the overall discourse has basically not changed, even if the language around it has been updated.
All the associated societal and moral ideas of what a 'good' and 'normal' family is and how they should behave as well as the attributes attached to them, and what a secure and nourishing environment for children means, become likewise constructed in these instances of their ethical opinions. Obviously, both ethics committees consider scientific evidence to be the most appropriate resource to support human rights and their ethical arguments, particularly by referring to (long-term) follow-up studies. Here, in the case of transgender persons, or as the other citation indicates, by referring also to family studies conducted independently of assisted reproduction that examined the family environment in which one parent was a transgender person.
These are vivid examples that reveal and perpetuate the imagined ideas of what should be considered a 'normal', 'good' and 'happy' family, and that all ART-applications are measured against this 'normality' of the heterosexual couple. It reveals merely the phantasm on which this industry is built, namely the 'nuclear family model' – consisting of a mother and father and their biological children living together in one household. It is presented as if this model would always and necessarily guarantee a good and warm family environment for children.
Despite their similarity of their approach and framing of these issues, both ethics committees construct them slightly differently in terms of the specific wording they use, their reasoning and the priorities they set. Yet, what they have in common is the *underlying logic* that drives their evidence-based argumentation. With the *logic of choice* also comes into being a very specific understanding of the way scientific knowledge and technology come together, which suggests a certain idea of professional responsibility:

> Within the logic of choice scientific knowledge is taken to be a growing collection of facts that gradually increases in certainty. Professionals need to know these facts. Preferably they should also add to them. Where appropriate they should be passing them on to lay people: one of their tasks is to provide patients with information. (…) I try to articulate how scientific knowledge and medical technology figure within the

> logic of care. What makes it difficult to do this, is that almost all discussions about knowledge and technology are framed in a rationalist repertoire. (Mol, 2008: 42)

In the above example of transgender persons and access to ART treatments, we see exactly this rationalistic logic at work, which then leads to such problematic justifications and to arguing with scientific evidence about the quality of a family (environment) or cohabitation, i.e. about morality. What we can see beyond this is how this kind of bioethical discourse actually makes the family (and its environments) and human reproduction at large amenable for (further) intervention, and therefore one can certainly speak of a technology of control and a power phenomenon in Foucault's sense with which he describes a complex web of relationships: Power is, according to him, a phenomenon that should be thought technologically, which means that makes something – things, objects, actors – productive; a power relation is able to create particular perspectives as well as strategic and productive relationships in the first place. In this sense, questions about access to treatments and on which criteria those are based are not easy to clarify, of course, for two reasons: First, it again touches on the basic claims of the field of reproductive medicine that oscillate between negative and positive rights (i.e., between liberty rights and claim rights).[97] And in this sense, there is always the question in the room: to which extent infertility actually constitutes a 'disease' (and how ART treatments are tied to such a definition or not). Second, and related, the field of reproductive medicine, and in particular this example about eligibility criteria for access to infertility treatments (based on gender identity and sexual orientation), shows the extent to which health is always a way of talking about morality, and the extent to which the concept of health changes in relation to approaches to evidence and ethics. Or to recall Virchow's famed observation: "Medicine is a social science, and politics is nothing else but medicine on a large scale" (as cited in Armstrong, 2006: 869).
In the ethics papers, one can observe these kinds of conceptual changes in relation to health, evidence, and ethics. Therefore, I will now move on to another example in which I consider a different but connecting aspect of issue-making in the justificatory work of these ethics committees: the temporal aspect as a central variable in the context of (in)fertility treatments.

7.1.2 The co-production of scientific evidence and morality: How oocyte cryopreservation becomes transformed into an issue of temporality in the bioethics discourse

> At the heart of the case I have explored was a tool of democracy, a condition of possibility, which took part in displacing and unsettling a technical object, which reworked the object into an issue. (Asdal, 2008: 23)

I chose this quote for the beginning of this section because it focuses on how certain institutions create and develop conditions that help unsettle a technical object and thus make it amenable to modification. My work takes this idea but instead focuses on sites outside of ordinary

[97] Negative rights are liberty rights which state that third parties are, in principle, not allowed to interfere with the decisions/choices of an individual. A right to reproduce means, for example, that enforced sterilization of (competent) person is not justified. A positive right is a claim right, i.e. the right of a person to receive help from others in achieving certain goals. In the area of reproduction, this would mean, for example, that infertile persons have a right to access medically assisted reproduction (see ESHRE, 2014: 1860).

political institutions[98] and follows the central claim that these are the places where significant political events, discourses, and thus transformations, take place, too.

Oocyte cryopreservation is a technology that was re-evaluated around 2012 by both ethics committees (and the organizations more broadly) in view of a new technique called 'vitrification'. It is besides IVF itself and PGD definitely one of the most important technological achievements in the field of ART. In the face of an obviously more efficient method of cryopreservation, which made this practice a more or less acceptable and therefore stable method and has become widely used in clinical practice, there are still a lot of challenges, as the ASRM has noted: "(...) in interpreting the literature regarding the efficacy and safety of OC" (ASRM, 2021: 37). Vitrification is a rapid cooling technique that, unlike previous slow freezing techniques, results in minimized ice crystal formation and leads to better outcomes (i.e., the efficacy of vitrified oocytes is non-inferior to fresh oocytes, according to these societies). And it is precisely for these reasons that it has become established clinical practice:

> The inefficiency of conventional slow-freezing techniques has for decades prevented the widespread implementation of oocyte cryopreservation in clinical practice. The introduction of oocyte vitrification significantly advanced the outcome of oocyte cryopreservation resulting in outcomes comparable to those achieved with fresh oocytes, as reported by experienced centres (Cobo et al., 2010; Rienzi et al., 2010). (ESHRE TF 18, 2012: 1)

As already detailed earlier in chapter 6, the reassessment of the efficiency and effectiveness of cryopreservation in light of this new technique (vitrification) has opened up different possibilities for its application, and the respective evidence production around it has likewise led to the removal of the experimental label of 'egg freezing' by ASRM as a major actor in this field. In addition to these technical aspects (such as demonstrating the efficiency of this technology and the achievement of better results with scientific evidence, etc.), they also provide the necessary justification work and social embedding that must be done in parallel when establishing a new technology in practice. This is what creates the necessary robustness in the first place, which can then serve as the basis for a technology's wider acceptance, because it provides arguments to which one can refer legitimately in the discourse.

In a fairly recent paper from 2021 by the ASRM Practice Committee, the aim of which is to provide an evidence-based guideline for planned OC[99], they summarize their justificatory work for removing the 2012/13 experimental label on oocyte cryopreservation as follows:

> Oocyte cryopreservation was limited to investigational protocols until 2013, at which point the American Society for Reproductive Medicine (ASRM) Practice Committee stated that oocyte freezing is not "experimental" and allowed for its routine use in postmenarchal women facing gonadotoxic therapies (2). (…) In recent years, the use of OC has greatly expanded not only for women facing gonadotoxic treatments but also for other indications, such as delaying childbearing, as well as for the purpose of oocyte donation. The Ethics Committee of the ASRM has suggested that the appropriate terminology for OC for these other indications should be designated as "planned OC. (ibid.: 37)

[98] Because Asdal's focus has been on public administration as an institution directly related to government.

[99] "Evidence-based outcomes after oocyte cryopreservation for donor oocyte in vitro fertilization and planned oocyte cryopreservation: a guideline" by the Practice Committee of the ASRM, In: Fertil Steril 2021, pp. 36-47.; https://doi.org/10.1016/j.fertnstert.2021.02.024.

This reassessment likewise led to a repositioning of how to classify the practice itself, including the expansion of the use of other 'non-immediate' medical indications (such as delayed childbearing, oocyte donation …) than gonadotoxic therapies, which ASRM had suggested to label as "planned OC". Or as ESHRE has called it, "age-related fertility loss", to indicate at least this one further usage case of OC in case of non-immediate medical indication. These are two important linguistic subtleties to which I will return soon.

The efficiency of vitrification is such that its outcome is no longer inferior compared to the outcomes that are achieved with fresh oocytes. This has prompted the committee to reconsider the entire practice and to argue for a different conclusion. They argue that the practice is now ready to practice on a broader level even when including all the other indications: immediate medical but also so-called social or non-medical reasons or, as ASRM would say, non-immediate medical reasons, which means the anticipated medical indications that could take effect or materialize at a later stage in life.

However, the efficiency is demonstrated using a bunch of scientific evidence, which indeed makes considerable sense in this case. They list a substantial number of studies, inter alia, the ones conducted by ASRM's practice committee itself as a leading actor in the debate around lifting the experimental status of OC. They primarily determined through evidence and the technical details of how the technology functions in contrast to the older slow freezing technique its effectiveness. In the case of the ESHRE's ethics group, this all became subsumed under a heading called: *"Background and facts. Effectiveness and safety of oocyte cryopreservation"*. In this section, they further point to the fact that the data seems to assure the safety of the procedure. However, there is no data on long-term follow-up of children.

In a last instance, they stress a study on "potential users' interests" (ESHRE TF 18, 2012) conducted in Belgium, which indicated that a substantial proportion of younger women would consider the idea of preserving their reproductive potential, which they use to substantiate the societal desirability of the technology. Accordingly, the societal desirability argument nicely illustrates how a particular technology frames the options and the corresponding discussions around it. Technology is indeed an inventive mediator that enables or co-produces the options and then frames the discussions around them accordingly. It even has the potential to modify the issue itself, i.e., what seems conceivable, discussable, defensible, and thus feasible, as well as desirable, in light of this new technology.

In the case of their debates around oocyte cryopreservation, they have reached another level of issue-modification. Even at first glance, the titles of the ethics committees' papers suggest that the issue at stake is not straight forward either. ESHRE, for instance, called its paper: "Oocyte cryopreservation for age-related fertility loss" (2012), while ASRM titled it: "Planned oocyte cryopreservation for women seeking to preserve future reproductive potential: an Ethics Committee opinion" (2018) (emphasis added). Even the naming of these documents shows already how differently the topic is approached and indeed modified: how differently it is enacted by framing it in specific ways by both of the committees.

One striking difference constitutes the distinctive *temporal* conceptualisation of looming infertility. EHSRE speaks about *'fertility loss'*, which involves a rather passive condition that can

occur to someone, in this case to women who wish to have children at a later stage in their life. Whereas ASRM has chosen the expression *'preserving reproductive potential'*, which has a much stronger focus on becoming active, so something that can be effectively avoided by acting upon when using this new intervention, consequently making something productive. This active and passive conceptualisation of the issue involves primarily a *temporal dimension*, in the case of ASRM, it is quite explicitly expressed when including the *planning aspect* already in their title. I would like to quote a section in which the ethics committee of the ASRM explicitly problematizes the *indeterminacy of terminology* and the *temporal aspect* that together are said to govern this practice:

> The appropriate language to describe the process of preserving oocytes for future fertility is unsettled. (…) When OC is used in contexts other than to avoid immediate gonadotoxic effects, observers have criticized terms like "social egg freezing", "freezing for non-medical reasons", and "elective" OC as trivializing and insufficiently respectful of the fact that the treatment is being undertaken to avert infertility that, if it arises, will in fact be a medical condition. The Ethics Committee concurs. Researchers in the UK have suggested the term "oocyte cryopreservation for Anticipated Gamete Exhaustion" or "AGE". The Committee believes a more general term is merited, however, because the circumstances that lead to use of the oocytes may be other than maternal age. The critical difference between the oocyte cryopreservation examined in this Opinion and that which is done when gonadotoxic therapy is imminent is its **non-emergency nature**. It is being undertaken as a **matter of planning before a medical indication has materialized** and will be referred to as "**planned oocyte cryopreservation**" or "**planned OC**". (ASRM, 2018: 1023; emphasis added)

ESHRE, in contrast, problematizes merely implicitly the *indeterminacy of terminology* and the *temporal aspect* that together are said to govern the practice of oocyte cryopreservation. They do it rather in the form of a general principle-based argument, which is in line with their style of thought; they do this alongside the medical principle of *'beneficence'*, the principle of 'doing good', which according to them reads as follows:

> (…) it belongs to the Hippocratic core of medical ethics. It is traditionally related to an account of the good of medicine understood as preventing and curing disease (and caring for the ill). Reproductive medicine is widely regarded as fitting in with this medical model, even though many fertility treatments do not restore natural fertility but aim at avoiding the consequence (involuntary childlessness) of compromised reproductive functions. (ESHRE TF 18, 2012: 2)

And further:

> The second, more fundamental, argument is that the appeal to the limits of medicine wrongly suggests that notions of health and disease can simply be inferred from facts about biological functioning without reference to socially mediated understandings (Richman, 2004). (…) Nevertheless, these treatments [IVF with donor oocytes] are regarded as **beneficence-based responses to a medical indication**. This **presupposes a wider understanding of reproductive health** in the light of which **fertility preservation for ovarian ageing** cannot so easily be dismissed as a non-health-related preference. (ibid.; emphasis added)

This shows a different way of ordering and modifying the issue, even if it ultimately comes to very similar conclusions and recommendations. Again, if we think with Foucault, who understood the main workings of discourses not as signifying elements referring merely to representations and contents but as practices that systematically form the objects or matters of which they speak, we can observe exactly this concept at work in the professional discourse around cryopreservation.

In the first case, that of the ASRM, the issue is negotiated at a level of terminology and, at the same time, its particular temporal and situated context gets constructed. This represents again a kind of co-production of the social and the medical, tinkering simultaneously with the formulation, definition and framing of this practice. They clearly highlight the non-emergency character of this practice as its main characteristic, which narrows down the whole issue in a specific way and produces a very special term and thus understanding for it. They define this practice very specifically in terms of its preventive and planned (future-oriented) character, thus narrowing down the object and coining the term "planned oocyte cryopreservation" to describe it, which allows for a special kind of intervention by patients and health professionals alike: namely, that young, healthy women freeze their fertile oocytes for a later 'emergency' case. That means it is not just about maternal age (or ovarian aging as ESHRE has put it) that constitutes this practice, which has not yet materialized as a medical condition but will definitely come to be if one does not act before it occurs. It is precisely this temporal category of "non-emergency" as a form of anticipation that is key to their problem definition. An illuminating way of reworking the issue, this is indeed an instance of issue-modification (Asdal & Hobæk, 2020).
In the second case, ESHRE delves into the common principle-based bioethics discourse, but not necessarily for the sake of resolving it as a conceptual category per se but rather situating it in its meaning in the context of a contemporary biomedical model and thus raising it to a different level. To this purpose, they construct the issue by raising the question of the place of fertility treatments within a contemporary Western medical model of curing and preventing disease, caring for the ill, and promoting health. Thus, they not only highlight the obvious conceptual fuzziness but further raise the question of the fluid and blurry nature of the medical and the social (as in the Virchow quote above).
By emphasizing the preventive nature of oocyte cryopreservation in terms of age-related (in)fertility (ovarian aging, as they put it) in this blurred socio-medical (in)fertility context, ESHRE, much like ASRM, concludes that it is not permissible to dismiss this practice as a non-health intervention, thus making it amenable to medical intervention in the first place – as a discursive legitimization.

The differences in shaping and modifying the issues through naming, renaming, defining, embedding, and containing, but also enabling practice(s) around this technology (oocyte cryopreservation for planning reasons) are subtle at first glance, but they become very apparent upon closer inspection. EHSRE indeed has a clear focus on the maternal (ovarian) age, which places the focus on the reproductive function of a female body, whereas ASRM put it on the planning aspect of using this procedure by effectively avoiding diving into a deep philosophical discussion of what medical treatment actually means and which position fertility treatments have in such a contemporary model of Western healthcare, or how the biomedical field of reproductive medicine is even actually involved in re-defining and indeed modifying this model of health and disease as well.
Maybe this is predicated on the assumption that you cannot separate the social and the medical when it comes to IVF and reproductive medicine, but which is also quite generally the case in

biomedicine. ESHRE, in contrast, indeed opens up the intricate question of the entangled nature of the social and the medical here, and thus, also the difficulty to separate 'values' and 'facts' in this regard, which has to be considered in these decision-making processes. However, what is clear is that, in both cases, the 'limits' of biomedicine, or its jurisdictional areas, become problematic in this domain. It is under negotiation, but that negotiation is handled differently in both cases, as one can see from these illustrations of their issue modifications.
This shows which different positions, roles and valuations are possible in this bioethics discourse on the different uses of oocyte cryopreservation. However, another commonality is the unifying element of the *temporal aspect* that makes this technology a productive intervention in the first place. In one case (ESHRE) it is located, so to speak, in the biological object itself (ovarian aging), while in the other case (ASRM) it is attributed to the woman as a subject capable of action when speaking about "planned OC". This again reflects the logic of choice as a very potent power relation in this medical context, which makes interventions in the present possible and productive, but aims predominantly at a goal in the future, namely: the preservation of a somewhat indeterminate reproductive capacity.

A logic of choice produces certain questions and answers:

These modes of justification are therefore socio-politically shaped, i.e. co-produced with an underlying logic, namely that of choice, but are simultaneously influenced by the respective reproductive technologies that open up these new possibilities. In a way, this makes sense, when we think, for example, of the critique expressed by Evans (2012) that principlism is a good fit for particular problems and questions in a research, or possibly a clinical context, but not so much so in others, such as societal and ethical questions like: Is a particular technology actually desirable, and if so, for which (exact) purposes and usages? This basically constitutes a question about the 'end', and not the 'means', the latter being primarily the framework in which they discuss these questions. All these ethical considerations tend to start with the fact that a technology is 'desirable', because of its potential usefulness, in one or another way, so they rather raise questions about the implementation of a technology: for whom, under which conditions and who decides that by which means? This is precisely why an ethics committee decides to consider new medical technologies or other related issues in this area (such as above: access to treatment for certain people or the expanded use of oocyte cryopreservation for "social" (ESHRE), or "planning" (ASRM) reasons) to be considered with arguments and justifications that are much more situated in the context of scientific evidence. This evidence will often be referred to as facts, definitions, and background that suggest some kind of closure and are thus an interesting instance of boundary work.

For both examples provided above, one can easily recognize how the issues become construed as supposedly scientific issues when justifying them using scientific evidence. By explaining and situating medical care in ART for transgender people primarily in the context of scientific evidence, it receives a very technical frame and becomes equally scientized. Of course, it is

clear that medical care has to be viewed in the context of current scientific developments and medical practices, especially when it comes to the safety issues of a treatment and technology. However, the question of if transgender people should have access to, and if so, under which conditions and what has to be considered for their safety in terms of adequate care and fertility preservation is an altogether different one. The first part, the question of access to treatments, cannot be answered in the language of scientific evidence, and we have seen what happens when an ethics committee decides to go down this road of rationality. It results into a rather problematic inference and co-production of empirical scientific evidence and morality, which leads to the justification of a certain morality regarding "good family cohabitation" with empirical evidence. The second part of the question, on the other hand, must be evidence-based, but not exclusively, because it is a question of good patient care, which is much more and cannot be reduced to mere scientific evidence-based knowledge and information.

Mol has reminded us of the potential problems that are involved here and clarifies what good care means in the very practical context of a clinician's consulting room:

> Complex stories, in which facts and values intertwine. Surprising stories, in which technologies do not live up to their promise. Stories with strange twists and turns that are difficult to understand. Usually, these complexities are cast as distracting disturbances. They are taken to be signs of the messiness of mundane practices that fail to submit to theoretical ideals. (…) Should clinicians indeed feel embarrassed about the gap between well-ordered theories that tell them how to handle science and technology and the far messier practices in their consulting rooms? Is it appropriate for managers to express disdain for what they call the 'unruliness' of doctors and nurses? Maybe not. Maybe it is time to (…) think about revising our theories about scientific knowledge, medical technology and the tasks of health-care professionals. (Mol, 2008: 43)

What the two examples of issue-modification have shown, healthcare is not just about facts and how to best handle technology and patients, but it is likewise about messy practices, 'unruly' people as well as non-human and technological actors in their situated surroundings – and especially their various interplays. Just as people are different, treatments must necessarily be diverse and adapted to the respective constitution. What has also become visible is the ethics committees' ability to modify and set issues through their documents, that is, the capacity to effectively transform objects or technologies and their uses into particular kinds of issues: such as the definition of cryopreservation as a technology of prevention, which is basically defined in temporal terms, from which quite different questions arise (or can be raised).

Therefore, in the next section, I will consider two intersecting, but completely different levels to which such health and thus ethical considerations are mostly directed: public health and individual or patient-centered health. In doing so, I will point out the potential for conflict that arises between these levels.

7.2 Modifying work and different contexts: How individuals and collectives relate to each other in bioethical discussions

The problem of this strict separation between values and facts in healthcare becomes particularly evident in the bioethics discourse when it comes to the relationship between the two levels, that of the *collective* (usually in the form of public health that addresses rather the population of a given society) and that of the *individual* (patient-centred) and how they relate to each other. Bioethical considerations often involve balancing between these two levels in the form of the two ethical principles of *justice*, which is rather society-related, and *reproductive autonomy*, which is clearly individual-related and almost nonsensical at a societal level. These are completely different levels that are difficult to combine, or at least they do not develop and improve each other in parallel. Public health considerations refer to the collective level and always aim to improve and preserve the health of the already healthy (the population) and are not necessarily designed to take care of those who happen to have a disease (Mol, 2008).

To return again to ESHRE's ethics paper on "Oocyte cryopreservation for age-related fertility loss" (2012), they have written in their abstract that these technoscientific developments have led to new debate within the professional community as well as in society at large. The debate primarily centred around the general acceptability of fertility preservation (oocyte reserve for future purposes) in the case of so-called non-medical indications, drawing from their terminology. For instance, right from the beginning, they reject some arguments that were brought against the usage of this application by critics, by stating that those arguments are not convincing. Here, they indeed incorporate a kind of sociological and time-diagnostic narrative in their ethical evaluation of a new ART application, which aims to address a collective, societal level. In particular, they utilize the so-called 'medicalization' argument, which describes the tendency to seek medical answers to societal problems. The critique under the 'medicalisation' argument is mainly based on the assumption that, with this particular type of fertility preservation (due to 'non-medical', 'social' or, in ASRM's words, 'planned' reasons), the way that modern societies are organized is just perpetuated and the problems leading to infertility are not resolved. This makes, for example, different life plans incompatible, including having both a family and a career, especially in the case of women. In this respect, the ethics group of ESHRE only partially agrees with one scenario that entails such a fear that natural reproduction will be replaced by assisted reproduction at a later stage of women's lives, they argue:

> (…) the comparison presupposes that natural reproduction would have been a realistic option for the women involved. Where this is not the case, the other scenarios show that the option of using a cryopreserved reserve may in fact bring important benefits, not just to individual women (and their partners) but also to society. (ESHRE TF 18, 2012: 3)

These benefits would entail, as they further elaborate, an increase in declining population birth rates in developed countries or a lower use of donor oocytes, which entails higher costs and is much more burdensome for patients in psychological terms. They further suggest this practice (the usage of patients own younger cryopreserved oocyte reserve) because of "more cost-effective IVF in older women with a lower rate of chromosomal abnormalities" (ibid.).

It is here where they try to combine both levels – the collective and individual – in order to strengthen the justificatory advantage of this technology through its supposedly promising

character or at least through what is expected and associated with it. There are also critical voices being raised within the professional community, which state that this treatment option should not be seen as a solution to the problem of declining population birth rates in Western countries. Since there are multiple risks involved with late childbearing, natural reproduction should always be the first choice, according to both ethics committees and ART specialists quite in general. Thus, it is important not to promote ART treatments as alternatives to natural reproduction, according to them. One could say this is a typical biopolitical argument aimed at the population, but one could also speak of a phenomenon of biopower. Gehring draws our attention to the importance of this particular notion of bio*power* because it is always also about specific forms and expressions of power:

> It is not about >>politics<< in the narrower sense that we have to talk, but precisely about unintentional, historically contingent >>forms<< of effectiveness in the Foucauldian sense. (...) Bio-power is not >exercised< specifically. It knows no power holders – at most profiteers. It is not only in the actions, but already in the perception, in the communication, in the tangible senses. In the last instance, processes of power should therefore be thought strictly without perpetrators, otherwise one misjudges their force and reality-forming power. For this reason, too, I prefer the more abstract hypothesis of biopower to the action-theoretically inferior concept of biopolitics. (Gehring, 2006: 15; translated by the author)[100]

Biopower as a more abstract form exercised through a particular discursive formation may prove superior in examining the parallel developments in public health and medical ethics (Armstrong, 2006). The way that these ethics committees try to combine economic, societal and individual aspects in the context of ART treatments is telling, namely by balancing the biomedical principles of reproductive autonomy, justice, beneficence and non-maleficence. These are sometimes incompatible with each other, but after they have been taken into account, all appears well in the discourse. But, actually, this represents a kind of rupture as a sort of last equivalent point (Foucault, 1972). In doing so, they try to oscillate between the principled arguments of patient choice, as it were, reproductive autonomy; justice in the form of societal considerations, and potential *benefits for society*, which are primarily articulated in economic terms.

The issue of oocyte cryopreservation is certainly one of these topics that they discuss specifically from a societal perspective and draw on that perspective in order to justify it. This has to do with a certain societal narrative in which this medical technology is embedded: the simultaneous incompatibility, but also the desire to overcome that incompatibility and reconcile family and work in the context of the increasing life expectancy of people in modern societies, in what makes it seemingly so attractive for women and families in general (ESHRE, 2012: 3). Embedded within such a rationale, the application of this technology almost seems as

[100] *Original quote in German:* „Nicht über >>Politik<< im engeren Sinne gilt es zu reden, sondern eben über absichtslose, historisch kontingente >>Formen<< von Wirksamkeit im Foucaultschen Sinn. (…) Biomacht wird nicht eigens >ausgeübt<. Sie kennt keine Machthaber – allenfalls Profiteure. Sie steckt nicht erst in den Handlungen, sondern bereits in der Wahrnehmung, in der Kommunikation, im erfahrbaren Sinn. In letzter Instanz sollten Machprozesse daher strikt täterlos gedacht werden, sonst verkennt man ihre Wucht und wirklichkeitsbildende Kraft. Auch aus diesem Grunde ziehe ich die abstraktere Hypothese der Biomacht dem handlungstheoretisch unterlegenen Begriff der Biopolitik vor“ (Gehring, 2006: 15).

a societal as well as an individual necessity. Regarding public healthcare and its difference from individual patient care, Mol for instance has noted:

> Thus, what is good for a population need not be equally good for its individual members. And this is also true the other way around. Care given to the individuals who most need it rarely improves public health. (…) Individuals and populations need completely different types of care. (Mol, 2008: 69-70)

This is just as true for bioethical considerations as they aim to look at these issues on the one hand, from a meta-level that attempts to 'objectively' consider these different aspects by relying primarily on scientific knowledge (empirical evidence) and their well-established, quite malleable, but rather narrowly defined principles. On the other hand, they also try to capture specific problems by defining or specifying more concrete recommendations for practitioners, clinics, centers. This is what these ethics committees are aiming at with their literary productions, but applied in the context of individual clinics and medical practices, this might turn out to be difficult.[101] For instance, as a main responsibility of doctors, they formulate the aggregation of data, but this could turn out to be difficult since professionals would need resources and a specialized infrastructure to realize this. Second, it is quite different when medical professionals are confronted with individual patients in their daily work than when they think about a medical technology in more general terms and detached from individual patients, their situations and circumstances.

With generalized terms, I mean exactly the level of standardization that is characteristic of such bioethical considerations. Even though they include other sections as well, calling them 'specific considerations', including additional reflections, they continuously follow the same rationalist logic with their specific modes of justification in which issues get thought through, analyzed and justified. This might make sense for some issues within a certain scope, but possibly less so for others. Whether the above-mentioned makes any sense at all is a legitimate question – that is, to think of technology as detached from any situated practice because it is rather the concrete use cases or possibilities that make it a concrete concern in the first place. However, there is little room left to think differently about the various intricate questions that arise in the field of ART, since the framework seems to be already quite fixed, based on quite rationalized concepts.

To illustrate these different levels of being confronted with an issue or situation that has to be dealt with, Mol succinctly observed in her case study on diabetes clinics in the Netherlands:

> Or, to put it in the terms used in the logic of choice: not all technologies serve the same ends and not all ends are equally worthwhile to everyone concerned. Countering a simplified belief in 'science' as the answer to all questions, the logic of choice stresses the multiplicity of medical possibilities. This makes good sense. In its turn, however, the logic of choice simplifies the relation between means and ends. It suggests that, if you choose where you want to go, your technologies will get you there. However, in the consulting room it quickly becomes clear that technologies are not obedient means: they rarely subordinate themselves to their official ends. Instead of improving a single parameter, they have an excess of, sometimes unexpected effects. This is the case for all kinds of interventions. (…) The unexpected is not

[101] This could be an aspect for further empirical studies, if and how such ethical statements, guidelines and recommendations are applied in concrete practice contexts - in which concrete ways they become effective.

> included in the design of trials. (…) Technologies do more than is expected of them. What is more: they also change expectations. (Mol, 2008: 47-49)

It is exactly this very practical context of a consulting room, or a specific problem at a certain place, that makes a difference in assessing a concrete situation with its concrete interventions and their nexus: if and how to use an intervention (technology, medication, procedure, protocol …) in which ways and which contexts, especially in terms of ethics and ethicality. Here, in particular, we can recognize a further gap between meta-ethical reasoning and the concrete patient-doctor relationship, which can be again traced back to the value-fact problematic. In either case, it is clear that both levels have to be considered when it comes to the introduction and the scope of these new treatment options of ART. In the process of introducing a new technology, the whole medical configuration will inevitably be changed. This constantly changing configuration or assemblage in the field of ART can be mapped through and within these ethics papers: They can be read, in fact, as a kind of *genealogy* (despite or, as it were, because of the replacement processes in case of ASRM's ethics documents) of this constant 'progress' of the introduction, adaptation and modification of new interventions in medical (as well as research) practice.

This always gives rise to new questions and concerns, which both committees try to 'resolve' and thus evaluate in their ethical reports in a characteristic way: precisely on a rather general, not to say 'universal' level. This divide is also visible in the particular way that their argumentation unfolds, and their modes of justification: the specific combination of metaethical argumentation by weighing the principles of the individual (autonomy) and more collective (justice) level, which runs like a red thread through their position papers.

The logic of choice considers the relation between collective and individual in such a way that it starts from individuals that are added together and from this they form a collective. It frames individuals as components that build together a larger whole. This is done in two ways: in a market variant they are either framed as customers or in a civic variant as citizens:

> Each customer has individual demands and in the market these are added to create an overall demand. In the civic variant of the logic of choice that informs liberal democratic societies, the individual building blocks that make up the collective are called 'citizens'. Citizens exert influence by voting. Their votes are added together and the majority wins. Neither of these systems of additions is completely linear. (…) in the logic of care none of this makes much sense. This is because the logic of care does not start with individuals but with collectives. A variety of them. (ibid.: 57-58)

A logic of care recognizes the diversity of collectives in which patients are embedded and that people in general are more than an individual to improve. They are members of families, have colleagues and friends, live in a city, and many more; they are always – from the beginning – entangled in a web of relationships, which makes a difference in treatment and ethical consideration.

To give another example: In the case of the use of reproductive technology for sex selection for nonmedical reasons, the ASRM considered the issue in 2015 from a social justice perspective as follows:

> Sex selection for nonmedical reasons also may be thought to implicate the ethical principle of justice because it may result in significant gender imbalances in society, with resulting concerns about social stability. Other justice concerns are that medical practices enabling sex selection may utilize resources otherwise available for the treatment of infertility or that the practice may only be available to those with the resources to pay for it (…). (ASRM, 2015: 1420)

Gender discrimination and public health resources are obviously important concerns for them to consider when it comes to the application of sex selection. In this regard, they cite a 2004 study of parental gender preferences that concluded that there are essentially none, leading ASRM to conclude that there is no reason to be concerned about promoting a possible gender imbalance. In light of ongoing problems with women's equality in the United States (but not only there, of course), the whole issue of sex selection for non-medical reasons needs to be understood in terms of its implications for gender equality. They then briefly discuss China, as a point of contrast, and its particular social context, where there have indeed been strict biopolitical regulations in place, such as birth control, and population control that has clearly favoured male children, and where such treatment options would indeed cause (further) serious social inequalities and harms. Thus, they clarify that social context and local specificities matter considerably when considering the relationship between sex selection and gender discrimination when arguing from a societal point of view:

> In conclusion, ART practitioners who currently offer or decline to offer sex selection for nonmedical purposes do so against a varied ethical and legal backdrop. Recognizing reasoned differences of opinion, the ASRM Ethics Committee **has not reached consensus** on whether it is ethical for providers to offer ART for sex selection for nonmedical purposes. Arguments regarding patient autonomy and reproductive liberty have been offered in support of the practice. Risks and burdens of the procedure, gender bias, sex stereotyping and nonacceptance of offspring, efforts to guard against coercion, and issues of justice all raise concerns about the practice. **Practitioners must take care to ensure that parents are fully informed about the risks and burdens of the procedure** and that they are not being coerced to undergo it. Because **the practice is so controversial**, **clinics are encouraged to draft and make available written policies** setting forth whether and under what circumstances nonmedical sex selection will be available. (ASRM, 2015: 1420-21; emphasis added)

Here we can observe what Mol has highlighted in terms of the differences between the goals that consider public health and those directed at individuals who, in the logic of care, are in fact part of different collectives. It shows that what might be considered ethically acceptable in one context is not necessarily acceptable in another one (public health vs. individual care). For example, if one looks at the whole issue from the perspective of reproductive autonomy, the practice of sex-selection for non-medical reasons seems very much ethically acceptable. Especially if the patient is understood as a 'customer' in a market logic or in a civic version as a 'citizen' who only needs to be sufficiently informed and provided with an offer and can then make a decision based on this information (like a vote). If, on the other hand, the practice is viewed from a socio-political perspective (in this case, justice considerations such as gender equality), there is a considerable risk involved in reinforcing coercion and gender gap issues, which would be detrimental to all of us on a broader societal level. However, the attempt to reconcile these two levels – the individual and the collective – very often leads to so-called dilemmas.

On the contrary, EHSRE problematizes the meaning of 'medical reasons' itself and argues for a wider delineation thereof, which reads as follows:

> Specific recommendations include the need for a wider delineation of accepted 'medical reasons' than in terms of avoiding a serious sex-linked disorder, and for a clarification of the legal position with regard to answering parental requests for 'additional sex selection' in the context of medically indicated preimplantation genetic diagnosis, or routine PGS. (ESHRE TF 20, 2013: 1)

Therefore, both committees were unable to resolve these issues, meaning in this context, that they were unable to reach a consensus. This led them to delegate this decision to the individual domain of the clinicians and practitioners themselves and claiming it their professional responsibility. ASRM's ethics committee only deem it as their professional responsibility to formulate general recommendations on the basis of which clinics should decide if they themselves will offer a particular application or not. The basic recommendation to clinics is to draft and make available written policies that should define under what circumstances sex-selection for non-medical purposes will be available. The practitioners have to decide which level and scope should prevail in their own context.

When it comes to the controversiality of the issue or the non-compatibility of perspectives – as they call it – they refrain from defining a clear setting or offering explicit conditions under which the practice would be ethically acceptable from their professional, i.e. a rather general point of view. Instead, they claim, it depends on the social context into which the practice will be introduced and embedded and this cannot be generalized, which constitutes an interesting move. In this case, they promote and argue for a strong form of self-regulation, which implies that the practice of sex-selection must be situated in its individual clinical and socio-medical context and application. This is indicative of a *strategic rupture* of and within this discourse to refer to a weak notion of 'information' (i.e., informed consent) – "to ensure that parents are fully informed" – and to a vague phrase of "written guidelines or policies" deemed as an adequate response to solve the problem, the so-called "controversiality" of this practice.

Another example of the difficult relationship between the collective and the individual would be a global pandemic (such as Covid-19), where the necessity to balance collective and individual health needs is greater than usual, especially in light of scarce resources. In an extremely contemporary ethical statement, the ASRM ethics committee specifically addresses this gap between the public and the individual levels of reproductive and infertility care in light of the Covid-19 pandemic. In that statement, they try to delineate "(…) an ethical decision-making framework that is necessary to provide reproductive and fertility care responsibly in times of public health crises" (ASRM, 2022: 1). Furthermore, they assess the responsibilities and conflicts that practitioners may face in light of scarce resources, the necessity of rationing them, and the counselling of patients in the context of quickly processing information regarding emerging threats to fertility or pregnancy (ibid.).

Even though, as they mention, many ethical reflections are not new to the novel coronavirus, despite that it has presented significant challenges for the field of reproductive medicine. Previous viruses such as the Zika virus, H1N1 influenza, or HIV posed similar challenges for clinicians practicing ART and fertility care. However, they conclude that public health crises

often require a shift of framework with particular attention on the need to maintain public health. This means that it shifts the focus away from the traditional biomedical principles that usually focus rather on individual health needs and guide clinician-patient relationships (autonomy, beneficence, non-maleficence). It directs the focus towards strategies that seek to balance individual patient care while simultaneously safeguarding the health of a population, i.e., towards a public health ethics approach. In summary, they discuss in particular the following three potential conflicting areas that need to be balanced in such a situation, which is characterized by scarce resources and the need of rationing them:

> The tension between **public health ethics** and **individual patient needs** can be dramatic when rationing is required. (…) The mitigation strategies to reduce these tensions include the constant reassessment of public health conditions to determine when and how to reinstate fertility care safely, recognizing when the allocation of scarce resources is unjust, and advocating for access to care for at-risk populations when fertility care can be safely provided. (ibid.: 2; emphasis added).

Here we see how priorities (must) suddenly shift in the face of a public health threat. It is remarkable to note that it is primarily this *label of controversiality* that makes an issue into more of a public health matter in bioethical deliberations. This label is, in turn, bestowed by these committees and their reports themselves, which leads to their non-consensus or dissent (as a position). The label of *controversy* functions as a *central concept* in bioethical debates because, first, it has already a reassuring effect (socially speaking) and second, it can be used to provide different possibilities of evaluation and/or positioning oneself within this discourse by anticipating to work through the problem and without committing to a specific position. Or, in other words:

> Interpreted as a [real] experiment, bioethics would thus be a paradigm for how, in the field of normalization and the change of the normative habitual, trial stages can be set up, as it were – not only for working through existing conflict issues, but also and especially when it is a matter of implementing new conflict materials. Ethics does not have to, but it can help to work this conflicting material down, to adapt them to public opinion, and perhaps even to educate the public [and policy-maker] prospectively: by means of the anticipated play of the expert dispute, one should learn what future normative worlds might look like, before the debatable play or object [technology] then comes on stage, i.e.: when the legislator becomes active. (Gehring, 2016: 159; translated by the author)[102]

This is an interesting way of thinking about bioethics and its functions: On both sides, that is, on the side of professionals and experts, and the public (patients, or concerned people), bioethics could act as a kind of rehearsal stage for learning and educating about what future normative worlds might look like. This is done primarily through their justificatory work, because these modes of working through conflicting material provides a set of arguments with which the public, as well as policy-makers, can operate and approach these emerging

[102] German Original: „Als [Real]Experiment gedeutet wäre Bioethik somit ein Paradigma dafür, wie sich im Bereich der Normierung und der Änderung des normativ Gewohnten gleichsam Probebühnen aufbauen lassen – nicht nur für die Abarbeitung existierender Konfliktthemen, sondern auch und gerade dann, wenn es um die Implementierung neuer Konfliktstoffe geht. Ethik muss nicht, aber sie kann helfen, diese kleinzuarbeiten, an öffentliche Meinungslagen anzupassen und vielleicht sogar die Öffentlichkeit prospektiv zu erziehen: am vorgezogenen Schauspiel des Expertenstreits soll man lernen, wie künftig Normenwelten aussehen könnten, bevor das fragliche Stück dann auf die Bühne kommt, sprich: der Gesetzgeber tätig wird“ (Gehring, 2016: 159).

technologies (or their new areas of application). As we have also seen in the previous examples, for instance, when it comes to negotiating what is seen or 'defined' as health and disease in the context of technologies such as cryopreservation, for so-called 'non-medical' reasons, but also more generally. Or when it comes to questions surrounding access to ART treatments for transgender people, or public health considerations in the context of health crisis.
However, the nexus between public and individual health needs in these ethics papers is intricate because they strive to satisfy both, which turns out to be difficult with an predominantly individualist decision-making system (except the justice principle) and the particular modes of justification they use. As we have seen, both levels are important but need completely different reflections and care. Clearly, in the case of these bioethical opinion papers, care cannot be identical with what Mol described in the context of specific doctor-patient relationships in diabetes clinics in the Netherlands. Ethical statements are something fairly different and very specific objects, located at a more general level of considering healthcare issues and technologies (and their potential for conflict). Indeed, within these papers, they sometimes aim to establish a kind of universal discourse but also attempt to stake out different positions. These positions can be taken (and are proposed by them) as different understandings of how to deal with conflicting issues from a bioethical point of view (i.e., how to think, speak, and act upon them). Moreover, the strategic ruptures and incompatibilities in the discourse have also become apparent, as I have tried to show on the basis of their justifications of cryopreservation for non-medical purposes.

Hence, in the next sub-section, I will further discuss how strongly the logic of choice, indeed framed as an ideal, prevails in these statements and reveals itself as a powerful form with a political dimension – bioethics is thus increasingly emerging as a specific form of governance (Gehring, 2006). I continue by illustrating how deeply ingrained this logic of choice operates in their ethical opinions and respective justificatory work therein and its potential flaws and gaps.

7.3 The problem of 'patient choice': Ethical pluralism and the principle of autonomy in the context of (written) bioethical decision-making

This bioethical discourse is mainly dedicated to formulating general frameworks, argumentative modes of justification, and common rationales through which practices in ART can be conceptualized and defined as ethically acceptable or, in rare cases, as unacceptable. This aims at being applicable to potentially different practice sites, such as different medical situations, various research areas and/or questions and even clinical and research settings.
Yet, this also implies that it is precisely here that the various questions become classified as ethical questions in the first place and where their various dimensions and aspects become (re)arranged. This is also where the logic of choice comes into play because it is obviously the logic that navigates quite generally and profoundly Western healthcare systems and thus also such bioethical considerations. I focus on this logic of choice in order to show how it comes into play within these ethical statements, as well as its possible collateral flaws and shortcomings.

Mol has reminded us that the logic of choice follows, to a considerable extent, a linear notion of time. This means that there is a clear difference between what is taken as given and what is deemed open for discussion. This holds true for both variants of a logic of choice, in which it is possible to treat patients as customers or citizens, but both undermine the ways of thinking and acting that are decisive to health *care*:

> Knowledge and technologies are given. They may change over the years, but they are fixed in the brief moment that matters: the moment a choice is being made here and now. Knowledge and technology make choices possible in the first place. But they fall outside the scope of discussion. You cannot choose for or against their existence: they are given, they frame the options that are available and thus they frame the discussion. What information might be worth gathering, or which technologies worth building is not a matter of choice for individual patients in the consulting room. This has been decided earlier and somewhere else. (Mol, 2008: 54)

This has profound implications for understanding technology and knowledge production in biomedicine itself because these earlier decisions that led to these technical objects are already shaping our perceptions of those technical objects. While this holds very much true, but at the same time, these are precisely the questions that both ethics committees partly aim to address in their position statements in specific ways. These questions are not necessarily about what kinds of technologies are worth building and designing, but at least consider which existing or emerging technologies are likely to prevail and under which conditions they might do so, while also taking into account the perspective of the people (women) affected.
Consequently, a special understanding of the profession, their duties and their tasks goes hand in hand with a logic of choice. Obviously, it becomes the exceptional task of professionals to provide their patients with good and adequate information, which means information that is based on scientific evidence. This means facts that establish a proper foundation for informed decision-making, which, of course, in this understanding, is the core of fulfilling the principle of autonomy. In Mol's words: professionals should properly implement the interventions for which their patients opt, and the patients are actually the responsible ones for managing their own health:

> Professionals should provide good information, and properly implement the interventions for which their patients opt. They should be knowledgeable, accurate and skilful. They should be capable of handling large quantities of information and able to act competently, but it is the patients who determine the direction to be taken. ***Patients manage, doctors implement***. (Mol, 2008: 55; emphasis added)

The logic of choice is obviously accompanied by a strong commitment towards a profession that is knowledgeable and skillful in managing a large quantity of data and can transform that data into adequate, i.e. understandable, information for patients, who, in turn, can use that information to make well-informed decisions themselves regarding the direction that their treatment should take. To stay once more with ESHRE's paper on OC – here they state the following:

> Women interested in oocyte cryopreservation should be **adequately informed** about the nature, burdens and risks of the procedure, the conditions under which their oocytes can be stored, the time frame within which they can be used, and the costs of procedure, storage and use. They should also be provided with **an estimate of their chances of successful reproduction**. This **requires state of the art data** about the

> expected oocyte yield per stimulation cycle and the percentage of life-born children per cryopreserved oocyte, stratified for women of different ages and with different ovarian reserve test results, **taking account of the literature** regarding the **use of specific cryopreservation techniques** (like vitrification or slow freezing). This information should also relate to the **expertise and efficiency of the centre**" (…). As a **precondition for informed decision-making**, women interested in oocyte cryopreservation should be made aware of the possibility of considering alternatives (…). (ESHRE TF 18, 2012: 4; emphasis added)

Although this statement was written in 2012, we can still observe that its main justification is primarily evidence-based and strongly linked with an underlying logic of choice – they are indeed co-produced. Subsequently, the well-informed woman must decide and manage the treatment path herself, and the physician or centre must then implement it in the most professional manner possible, which means in the most knowledgeable and evidence-based way. This perfectly fits a logic of choice model.

Of course, scientific evidence plays a vital role in assessing these biomedical technologies, interestingly also when it comes to their 'ethical' consideration. Anyway, the whole value complex is not explainable and determinable on the basis of scientific evidence. It only captures the technical part of a technology, its functionalities and outcomes, but not the social and ethical dimensions, such as whether, how, when and for whom with which consequence that technology would be desirable and applicable. These questions are rather successfully (re)located to the patient's side, which is then justified by the autonomy argument, as the major biomedical principle, which is readily invoked as an argument against paternalism in medicine. However, this presentation of 'facts' to a patient (which means informing the patient through the IC form) already contains a normative component because the technology and its respective treatment options are already assumed to be one of the appropriate pathways for a patient to take. Under a logic of care, in contrast to a logic of choice, these other aspects beyond just technical or knowledge-related qualities would be far more included in the overall decision-making process, as well as the specific technology itself as merely one viable pathway. This would then lead to more of a shared decision-making approach, as Mol pointed out:

> This is difficult in the logic of care. Here it is impossible to separate management and implementation. Attuning variables to each other is as much about establishing facts as it is about figuring out what to do. Using technologies requires that they be adjusted to each specific situation. Care is not a matter of implementing knowledge and technology, but of experimenting with them. (Mol, 2008: 55)

Of course, in STS, we are familiar with the notion of the *sociotechnical*, which emphasizes the entangled nature of the social and the technical. However, the justificatory mode of scientific evidence suggests a rather technical view of technology one that clearly favours a knowledge-based approach towards its evaluation, but which nonetheless falls short in specific ways when it comes to evaluating a technology in its full complexity (including its effects). To capture this full complexity, an assessment must necessarily be sociotechnical, which means relaxing the strict separation between *physicians dealing with facts and patients dealing with values*, which must necessarily be seen as interconnected and mediated.

Even though this strict separation (or the claim to separate) of the social and technical (or values and facts) underlies to a large extent also the *concept of value pluralism* and its

acknowledgment, at least in its libertarian form (Coggon & Miola, 2011). Coggon and Miola (2011), for example, have problematized in their critical analysis the all too often conceptual confusion between *autonomy* and *liberty* in the context of medical decision-making in English medical law:

> The **ritualistic nature of consent** (a patient is given a list of risks and she then makes a decision) has developed for good reason; the **courts' desire to prioritize patient autonomy**. Nevertheless, (…) we see an extreme but logical extension of the courts' thinking, and a sign of a **misinterpretation of what constitutes 'choice'** on the part of patients. **For consent, understanding must be a precondition**, as it is in the law relating to capacity. Future courts must recognize this and help patients to make real choices. The application of the law may not be perfect, but by addressing the correct principles it can be improved. (Coggon & Miola, 2011; emphasis added)

So far, I have only touched upon a logic of choice in its more general form, but to further specify how it functions in the two cases, I will now discuss the two variants it can take in Western healthcare systems: a *market* form and a *state* form. Both forms entail a certain conceptualization of the patient as well as their relationship with the professional: once as a customer and once as a citizen (Mol, 2008). Scrutinizing these differences and how they become realized within the written work of these ethics committees is a prerequisite to understanding the subtle nuances of their bioethical decision-making work.

ESHRE, for example, clearly follows a model of the state that implies that patients and professionals are equally considered citizens. This variant of a logic of choice is based on the idea of a contract that governs the relationship between doctor and patient. In contrast, ASRM operates more in a market logic, which considers the patient as a customer and which corresponds with the general commercialized nature of the healthcare sector in the US. However, this commercialization is, of course, not only in the US but there can also similar tendencies be found in most European countries, namely the tendency to structure almost every sector analogously to a "business ontology" (Fisher, 2009), including education.

Mark Fisher emphasized these pervasive capitalist processes, or as he called this pervasive atmosphere, "*capitalist realism*", which is gradually permeating healthcare, too:

> Over the past thirty years, capitalist realism has successfully installed a 'business ontology' in which it is simply obvious that everything in society, including healthcare and education, should be run as a business. As any number of radical theorists from Brecht through to Foucault and Badiou have maintained, emancipatory politics must always destroy the appearance of a 'natural order', must reveal what is presented as necessary and inevitable to be a mere contingency, just as it must make what was previously deemed to be impossible seem attainable. (Fisher, 2009: 17)

Indeed, if one follows Fisher's argument, one could say that the logic of choice embodies a kind of "business ontology" (depending on its precise formulation), because if healthcare must be run like a business, so too must it seem logical to view patients as customers to whom treatment options are offered, provided, and, ultimately, sold.

The specific shape of a logic of choice model becomes particularly articulated in the case of ASRM's ethical statements. In a replacement paper from 2022 (with the replaced version being from 2016) on the increased risks of complications during fertility treatment and/or resulting pregnancy, one can clearly see how this logic of separation works: "physicians implement,

patients manage". But there is an obvious twist because this logic sees patients as customers rather than citizens; that can be seen in the following passage:

> Whenever possible, physicians should encourage patients to reduce their modifiable risk factors. In cases where the patient is unable or unwilling to modify her risk, physicians may differ regarding whether or not to treat her. In such cases, it is acceptable for physicians to decline to provide fertility treatment when such **decisions are based on medical considerations** and applied **without bias**. Clinicians may differ about what constitutes **a reasonable level of risk** during fertility treatment or pregnancy. It is ethically appropriate to decline to provide fertility treatment when the physician determines that the risks of complications to the woman or her resulting child are unacceptably high, as long as such **judgments are made in a nondiscriminatory fashion and without bias**. (…) In addition to routine counselling in advance of initiating fertility treatment (…), endocrinologists should take particular care to counsel women about treatment – or pregnancy-related risks that are specific to their medical condition so that they are **able to make informed decisions** regarding their reproductive care. (ASRM, 2022: 713-714; emphasis added)

On the one hand, one can see here a strong emphasis on risk counseling, and on the other hand, the associated decision-making capacity on both sides: physicians as well as patients. However, it is clear from this extract that women undergoing fertility treatment who are at increased risk of developing complications need to manage their reproductive care by making well-informed decisions, and that professionals need to ensure that women are adequately counseled and informed about possible treatment options and, in particular, their potential risks, precisely so that the patients can make well-informed decisions themselves. In order to discuss some aspects specific to this case, I would like to provide another quote from the same paper, because it allows for a broader discussion of what it means (in terms of its implications) when a scientific society such as the ASRM follows this particular modality of a logic of choice, and especially since we can also observe here a slight conflation between the two notions of *liberty* and *autonomy*:

> **Reproductive liberty** is a core value in the provision of fertility care and includes the **right of individuals to make informed choices** about whether and how to reproduce. For those women at elevated risk who may need assistance in becoming pregnant, the **importance of reproductive choice** supports their access to treatment. (…) **The value of reproductive choice** is a primary consideration in favor of treating women at elevated risk. In such contexts, it is especially important to ensure that choices are made without pressure and are well informed. (…). In light of these concerns, **providers must work with patients** to explore their reasons for choosing treatment and their **understanding of the risks and alternatives**. Providers should make a reasonable effort to ensure that patients fully appreciate the risks to themselves and their potential offspring. (ASRM, 2022: 716; emphasis added)

They start by presenting reproductive liberty as a core value in the provision of fertility care to state in the next paragraph that the value of reproductive choice is essential when treating women at elevated risk. What is salient is that we can note the same tendency to conflate "the language of autonomy with the concept of liberty by insisting that the decision must be made by the patient", as Coggon and Miola have already noted in the context of English court decisions (Coggon & Miola, 2011: 536). The fundamental flaw here is that information per se does not guarantee that an autonomous decision is made; it only assures that the information has been passed from the doctor to the patient. Furthermore, in a very basic sense, I would agree with the two authors that, also in the context of ART and fertility care, autonomy rather relates to free will (i.e., self-government) and liberty rather to the freedom to act without the

intervention of a third party. Autonomy rather constitutes a moral concept, whereas liberty is a political construct – the freedom to act. Of course, both are crucial and are closely related, but should not, however, be confused, which the two authors emphasize:

> Both liberty and autonomy are important, but the maximization of one is not always harmonious with that of the other. Furthermore, mediating between the demands of each is made harder with a commitment to value-pluralism. (…) It is clearly right that people may have the mental competence [autonomy] to do things that they are not legally entitled to [liberty]. (Coggon & Miola, 2011: 531-532)

The difference and potential disconnectedness between autonomy and liberty to act is very crucial to consider in the context of patient autonomy and medical decision-making. As the authors have rightly pointed out, one could reach an autonomous decision but not have the liberty to act on that decision; or conversely, one has the liberty to act but is unable to make an autonomous decision for various reasons (e.g., insufficient understanding because mere information is not enough or a guarantee for understanding).
Liberty does not necessarily have more to do with market freedom, but since it focuses strongly on freedom of action in a very legal sense, it might indeed be more related to such a market logic and thus logic of choice. While autonomy (making the right decision for one's life based on proper understanding and not mere information) is indeed an essential difference to keep in mind when it comes to the logic of choice and its modes of action. Since these two concepts, if misapplied, can also cancel each other out, the two authors forcefully pointed out:

> There is an assumption that if a doctor lists the risks inherent in a procedure and then allows the patient to make her own choice based on that, her decision is rendered autonomous. This combination of autonomy and liberty may, at first glance, be seen as logically harmonious; an autonomous person without liberty is constricted and any enjoyment of liberty is severely curtailed if choices are not autonomous. Yet the two concepts can combine to cancel each other out, particularly if they are used in an unsophisticated form and without another key to autonomous decision-making; effective communication. While disclosure of relevant information is part of serving autonomy, it is not in itself enough. Other factors such as the patient understanding the information must also exist. (Coggon & Miola, 2011: 537)

For instance, back in 2012, ESHRE made also use of a classic example of a *patient choice argument* in the debate around the blurred distinction between medical and social reasons in which these ART practices are situated. In this regard, they mention the difficulty of assessing such technological practices from views about "the good life" because they always rest on kinds of "naturalistic" understandings. These opinions often end up endorsing stereotypes about what and how women should behave, about their roles in private and the public sphere, and diverse understandings of what a 'good' family actually constitutes and many more. Forcing such views on others in a secular (one could even say scientized) debate is, in their opinion, morally unacceptable:

> In a secular debate, the problem with arguing from views about 'the good life' is that they rest on religious or naturalistic presuppositions that not all participants necessarily share. As imposing such views on others is morally unacceptable, **fertility specialists should leave it to the women themselves to make their own informed decisions** about the need for fertility preservation. Indeed, doing so is in line with the **ethical principles of respect for the autonomy** of persons. It is accepted that competent persons have the right to make their own reproductive decisions, including whether to have children, with whom, how many, etc. It

> would seem that this also includes the right to decide about when to reproduce and what priority to give childbearing in relation to other life plans. (ESHRE TF 18, 2012: 3; emphasis added)

Here, ESHRE pretty much follows this particular choice-model that Mol has described as the 'state-model', which configures patients and professionals alike as citizens in relation to each other. A state and its civic laws frame relations between people as contracts that make them 'citizens', including specific rights and duties. Following or applying such a model in the biomedical domain aims to abolish medical authority in the form of a paternalistic approach. This is not bad per se, but it also brings its own pitfalls because people in a medical context are precisely not citizens in the first place, but patients who need the help of their doctors. Different roles, responsibilities, and needs also come along when citizenship becomes established as the standard in the medical context. Mol, for example, outlines:

> If I question the civic version of the logic of choice, my aim is not to frustrate the emancipation of patients. Instead, I would like to go beyond it. (…) The point is this: if patients in the consulting room are 'allowed' to become citizens insofar as this is practically possible, **citizenship is established as the standard**. At first, this may seem fine. Citizens, after all, are not bossed around by patriarchal rulers. Their contract stipulates that they are masters of their own lives. However, on closer examination **something seems to be missing.** By definition, **citizens are not troubled by their bodies. But patients are**. (Mol, 2008: 30; emphasis added)

If one follows this particular model of civic choice then this also involves that people having to control their bodies, because citizens have the duty to do so. Citizens are, by definition, instructed to control and tame their bodies, but as Mol has convincingly shown in her studies, disease or medical problems may significantly interfere with such an civic understanding of choice in the medical realm. This might cause several problems at different levels if one follows this kind of logic in healthcare.

In ESHRE's remarks above, we see this very idea of the patient as citizen at work: professionals/practitioners should not impose certain views on their patients in a paternalistic way, rather, the patient-citizens must decide for themselves because it is their right and duty to do so in this variant of the logic of choice. Mol, however, points us further to the problem that bodies are not trapped in causal chains and therefore in a *logic of care*, they need to be embedded in treatment practices, into specific therapies that meet their individual needs as patients, and not as citizens in the first place. That means, in a logic of care, it is rather about a collaboration between professionals and patients and about exploring together the ways of shaping a 'good' life with a disease, or a particular medical condition together, as it is the case with conditions of infertility.

Although, when looking closer, we recognize these slight differences between the both organizations, not just in a general style of articulating a logic of choice but also in the minor, more subtle aspects, e.g. what and how they use vocabulary differently. Whereas ESHRE speaks about *"respect for the person's autonomy"*, ASRM uses the notion of *"reproductive liberty"*. This suggests that there are slightly different models of the same logic at work. Actually, one could say that autonomy reflects more of a citizen-state model of choice, while liberty, in contrast, represents the condition of being free from control or constraint, and the freedom to act without interference from a third party, corresponding more with a market logic than with the

concept of autonomy. The term "provider" in the ASRM papers also underscores this market model of choice, even though the term "provider" is commonly used for healthcare services in the US context. However, that maybe signals this different conception (if we recall Fisher's argument of a 'business ontology'), and commonly that we are talking about services in the medical context. "The language of the market contains only positive terms. Products for sale are attractive. Tellingly and non-neutrally, they are called 'goods' (Mol, 2008: 28). This we can also notice in the examples provided above, whose language (both ASRM's and ESHRE's) is quite positive, and no one would argue in principle against their opinions and views, but nevertheless, upon closer inspection, it gets clear that it also reflects a positive language of the market or the state, where services are provided to patient-customers or patient-citizens with all the associated duties and rights.

Obviously, these are rather subtle nuances, but they are crucial to consider when it comes to the analysis of these varieties of a logic of choice and which one is at work in each case. Unquestionable, these differences are not pure and perfect and merely represent tendencies, namely situated modes of thinking and ordering infertility treatment and practices in ART. This, of course, also must be seen in the broader regulatory context of a European healthcare system versus a US healthcare system, which will be thematic in the upcoming section (7.4).

In both cases, and in the provided statements, they talk about patients' rights and, by implication, their duties, yet it is clear that in both models – state and market – there is a not insignificant risk of losing sight of the basic: namely, that those involved are patients first and foremost who need care, each individually. Here again, in these accounts, the problem with patient choice becomes visible as it manifests as a narrowness towards providing the 'right' information to patients, who then can base their autonomous choices on that information and take individual decisions based on what they deem adequate and good for themselves. However, good care needs specification and not generalization, categories should stay adaptable to individual needs: "The logic of choice assumes that we are autonomous individuals. The logic of care is attuned to people who are first and foremost related. While some of these relations cannot be changed, others can" (Mol, 2008: 62).

Albeit hidden, *moments of care* likewise become visible and gain importance in such ethical statements. For instance, when the ASRM ethics committee writes that "providers must work with patients to explore their reasons for choosing treatment and their understanding of the risks and alternatives" (ASRM, 2022: 716), with which they indeed underlie the importance of understanding the information that is provided to the patient; without that crucial ingredient, autonomous choices and decision-making is forfeited. This means *communication* and adequate disclosure and assurance of *understanding* thereof must be the basis for informed decisions – i.e. for the informed consent to act as the medico-legal protection of the autonomy principle. That is, good (equal, clear and responsible) communication within a patient-doctor relationship is of utmost importance to truly empower patients to make autonomous decisions and is not merely providing more and more information. This also seems to be recognized by these scientific societies and their ethics committees, but it would be necessary to consider these aspects much more profoundly with regard to the conditions of autonomous decision-

making and its potential reverse effects, which is by no means exhausted in the mere provision of information through an IC form.
Moreover, the informed consent procedure is based on a particular and historically predicated conception of human nature, which prioritizes and celebrates personhood within a specific politico-economic context (business ontology) (Cooter, 2010; Fisher, 2009). This shift towards autonomy signals a new psychological and moral way of making up people, replacing one 'truth regime' by another – "(…) namely, an ethics based on 'the social subject' to one grounded on 'the self'" (Cooter, 2010: 668). However, caution must be taken not to turn the concept of autonomy completely into its opposite, namely to individualize decisions that are not individual at all and therefore cannot be decided by the individual alone. This is also true in the medical context and within a patient-doctor relationship. This all-encompassing and rampant concept of autonomy makes us believe as if the individual could make any decision independently, if only one had enough and the right – of course: evidence-based – knowledge, but that this is not the case (in so many areas of society and life) is obvious.

Thus, in a final step of this chapter, I will now consider the boundary work that these ethics committees perform. To do this, I will view them in relation to their regulatory environment, in which the work of these scientific organizations in general and that of the ethics committees in particular is embedded and must therefore also be considered from this perspective.

7.4 Boundary work: Governance and self-regulation in the field of ART

The focus on the particular kind of boundary work they perform within these ethical opinion papers includes the question of how bioethics relates to politics and law, that is, how they position themselves in their ethical deliberations in relation to these other domains of thought, reasoning and regulation. In doing so, I take a closer look at the governance aspect as it is expressed in their bioethical decision-making work in relation to other oversight mechanisms. Thus, the question of self-regulation and governance in the context of ESHRE and ASRM as scientific societies has a great deal to do with their work on justification and how it relates to the regulatory environment in which they are embedded.
My study interest has been guided by the question: How do these two organizations (as professional communities) structure these debates and reach agreement or consensus on shared views and understandings, or sometimes also disagreement (dissent) about the 'ethical acceptability' that should guide research and clinical practice? And further, how is this negotiated, primarily in and through their ethical documents as an important communication tool to their members? A shared understanding within the committees and its membership in general is deeply related with their work on justification, developed by shaping and modifying the issues at stake (and their definition of ethical acceptability) in specific ways. These specific ways actually enact the issue itself as what it is then ultimately negotiated to be, which very possibly migrates not only within the framework of these societies but also outside the cosmos of these societies into various political arenas and practical contexts.

Their justificatory work can be understood as a very specific kind of *boundary work* that becomes materialized through this modifying work of an issue. This reflects simultaneously the agenda of these ethics committees and their work: *making an issue* means in the first place defining it by shaping, negotiating and limiting its contents and effective areas. Or as Asdal and Reinertsen put it recently, "In short, 'issue' can be understood as something open and contested, but also as something factual and settled" (Asdal & Reinertsen, 2022: 221).
In analytical terms, this means understanding things in their becoming and in how they are enacted as particular issues in and through their ethical reports primarily by their (argumentative) modes of justification. Besides the detailed analysis of justificatory statements, this also means studying how they try to make an impact but also how they position themselves in relation to policy actors and legislation and thus, how they position themselves relative to the political decision-making processes. In ESHRE's words:

> The collaboration with politicians and policy makers throughout Europe is part of our Mission and Vision. In our engagement with policy makers, we advocate for better policies for people affected by infertility and for professionals involved in medically assisted reproduction. Nothing about us without us! (ESHRE Website, 2022)[103]

This intended impact on policy actors, however, becomes articulated differently in the two cases. Against this backdrop, *two different models,* or rather *tendencies, of (self-)governance* can be identified in the case of EHSRE's and ASRM's (mainly written) ethical decision-making work. I would suggest that in the case of ESHRE, we see more of what I would call a (*self-)governance model,* whereas in the case of ASRM, we see the more classic form of medical *self-regulation* as already mentioned. With this difference in mind, I am trying to capture the distinctive levels on which they aim to exercise (self-)governance or to put it differently, their steering interests, on the basis of their particular argumentative modes of justifications.
I, therefore, aim to highlight on these differences and the relationship between these two tendencies of (self-)governance and will briefly outline what this has to do with the task of the 'self' in the work of these committees. And by extension, what this has to do with making human reproduction/infertility and its treatment a governable issue through the definition of ethical acceptability, in particular through the professional bioethical discourse on reproductive technologies.[104] This distinction can basically be located in a different understanding of the role and task of the medical professionals in the field of reproductive medicine: in the case of ASRM, there is a much more – what I would call – practice-oriented approach, and thus more of a self-regulatory model in place; whereas in the case of ESHRE, there is more of what I would call a (self-)governance model at work. Both of these approaches should be understood within a much broader discursive and medico-legal framework in which bioethical issues become problematized and such ethics bodies themselves are constituted.
Despite their claimed internationality and multidisciplinarity as scientific societies, both societies are embedded in specific geopolitical as well as socio-cultural contexts. The underlying difference in understanding the tasks of governance or (self-)regulation is partly contingent on

[103] See: https://www.eshre.eu/Europe (accessed on 13th May 2022).
[104] This is a thread that I will take up and have a closer look at in Chapter 8.

this socio-political difference: ASRM is situated in a US context, presumed as a supposedly more coherent or homogenous state entity in a medico-legal as well as cultural sense, whereas ESHRE is based in Belgium, and as a European international organization it is situated in a much more loosely connected legislative (as well as multilingual) space of the European Union.
That is the theory; in reality, the entity of a nation state in the first case does not say so much about the coherence and homogeneity of how a biomedical field, such as assisted reproduction and its related technologies (IVF and ART), are regulated by law. Vice versa, the presumed heterogeneity of a conglomeration of different countries to one economic unity (EU) does not mean necessarily a chaotic and unregulated limbo. Overall, both bodies of legislation can be characterized as a kind of patchwork when it comes to the regulation of ART. This does not mean that it is totally unregulated, nor that it is over-regulated, but it definitely means that it is difficult to give an accurate overview of what the regulatory situation(s) are in each country or member state in both cases. These regulatory cases range from supranational legislation such as EU directives and regulations, or federal law(s) in the US context, to country-specific (EU) or state laws (US), to 'voluntary' guidelines, recommendations and codes of conduct such as those published by these professional bodies. Nevertheless, I will summarize some of the key points of the regulatory landscape, by referring to ESHRE's collection of diverse fact sheets on the regulation of assisted reproduction in Europe and particularly in the context of EU member states:

> While patients in Europe have freedom of movement for treatment (under a 2008 European Commission directive), EU member states are free to enact their own medical legislations. This means that different member states have different regulations for the treatment of infertility, but that patients are free to travel abroad for treatment, even if their 'cross border reproductive care' violates domestic legislation. Although some aspects of embryo research and laboratory conditions are regulated by federal law, there is no national legislation for IVF in the USA. Practice is mainly led by guidelines of the ASRM (American Society of Reproductive Medicine), but all clinics are required by law to submit the data of each treatment cycle to a national registry. (ESHRE fact sheets 2, January 2017)[105]

This means there is no common EU medical legislation when it comes to ART but freedom of movement for treatment ('cross-border reproductive care'). Further, every country in the EU has some sort of legislation governing ART, but almost all are supplemented by professional guidelines. Legislation has usually been introduced or modified over the past 30 years in European countries (member states of the EU), which was often accompanied by controversy, according to ESHRE's fact sheets. There are legal differences between countries in, embryo selection, surrogacy, reimbursement of IVF, state funding, patient eligibility criteria (age, sexual orientation) and many others. The only common EU-wide regulation refers to the *EU Tissues and Cells Directive* (EUTCD) from 2004 and 2006 (with the latest update being from July 2022), which sets out requirements regarding quality and safety (procurement, storage, transport, traceability, infection screening) of tissues and cells in human applications and thus, harmonizes IVF laboratory procedures among EU member states. Between 2017-2019 there was an evaluation of this EU Directive on blood, tissues and cells, a process in which EHSRE and

[105] https://www.eshre.eu/Press-Room/Resources; and: https://www.eshre.eu/Europe/Factsheets-and-infographics (both accessed on 10th January 2023).

other stakeholders participated and actively contributed by highlighting existing shortcomings when it comes specifically to the field of medically assisted reproduction and the handling of these human materials in human application.[106]

In the US, the "Fertility Clinic Success Rate and Certification Act" (FCSRCA) of 1992 is the most visible and important ART-specific regulation at a federal level. This regulation requires all ART clinics to report their success rate data to the federal government in a standardized manner (ASRM, 2010; ESHRE, 2017).[107] Due to a strong form of federalism in the US, many other reproductive technologies are regulated via state laws. In their paper on the practice of nonmedical sex selection, ASRM states:

> While no state in the United States legally prohibits the practice of sex selection at present, it is worth noting that nonmedical sex selection is prohibited in Canada and in a number of European countries. Such regulations vary widely in Europe, and free movement within the European Union is a complicating factor (33, 35, 36). It is permitted in Israel by approval in rare cases (37). A 2008 report of the (now defunct) New Zealand Bioethics Council, Who Gets Born? argued that the practice should be permitted (38). (ASRM, 2022: 722-23)

Interestingly, they embed the respective social justice concerns regarding this practice into a geopolitical comparison between different countries and their various legal regulations regarding sex selection for non-medical reasons. However, the US is a wealthy nation without universal healthcare, its healthcare system is characterised by rather unjust access and distribution of medical treatments and drugs, in line with the maxim: who has the money has also the right to access and afford expansive treatments and drugs – one reason why some scholars have spoken with regard to infertility and their expansive treatments of a "boutique medicine" (Thompson, 2005). With regard to the biotechnology revolution, others have spoken about the prevalence of perceiving people, in the first place, as customers.[108] Charis Thompson succinctly has summarized the political context in which IVF emerged in the United States as follows:

> (…) low levels of federal regulation and a patchwork of regulations for reproductive technologies state by state; the absence of a universal healthcare system; and a politically partisan abortion debate that restricted federal funding for research. These factors together pushed most IVF into the fee-for-service healthcare sector. As a result, market dynamics took hold in US IVF, increasing the products on offer in a manner freer of common restrictions on price, family form or treatable diagnoses than in many other countries. (Thompson, 2016: 134)

Reproductive technology is a rapidly developing and constantly progressing field that has become more and more branched out and fragmented in the US. This has several reasons, but one can be explained with the lack of government-funded healthcare in general, which is "(…) both a product of and contributor to the attitudes of physicians towards government regulation of medical practice", which persists mainly in resisting government regulation (Bayefsky, 2016:

[106] See: https://www.eshre.eu/Europe/Governance-of-MAR-in-Europe; and: https://health.ec.europa.eu/blood-tissues-cells-and-organs/tissues-and-cells_en#latest-updates (both accessed on 10th January 2023).
[107] See also: https://www.cdc.gov/art/nass/policy.html (accessed on 11th January 2023).
[108] See, for instance, the TEDxBaltimore talk by Ruha Benjamin: From park bench to lab bench - What kind of future are we designing? https://www.youtube.com/watch?v=_8RrX4hjCr0 (accessed on 20th November 2019).

44). As a consequence, medical care in the US is largely-market driven and assisted reproduction is in particular directed by market forces rather than a top-down regulatory approach (Spar, 2006). Other explanations for this fragmentation, such as those given by former ASRM leaders, include that a government that does not provide any funding, also lacks the right to regulate their practice (Simpson, Rebar, & Carson, 2006). Bayefsky observes:

> In a paper written by past presidents of the ASRM on the regulation of PGD[109], the authors state that they 'espouse self-regulation, eschewing legislative mandates' (Simpson et al., 2006). They concede that they 'might feel differently if assisted reproductive technology were funded entirely by the government' since 'If the US government or a state were to fund IVF and PGD fully, one could agree that the right to regulate would increase proportionally'. (Bayefsky, 2016: 44)

The ASRM's self-understanding can be inferred in part by their strong (argumentative) commitment to the IC procedure. ASRM pretty much exercises self-regulation in a classical sense, to act or regulate oneself on itself, controlling from within the medical community without much external authority (and without legislator or government intervention), because they constitute this kind of authority together with their auxiliary partner organisations in the field of ART in the US context. This is possible because of the largely 'absent' federal legislation (except for the "Fertility Clinic Success Rate and Certification Act" (FCSRCA) of 1992).
This is contrary to the practice in the UK, where National Health Services (NHS), which is one of the largest publicly funded health services in the world, directly employs most physicians and, as such, holds the right to regulate medical practices. As a result, physicians in the US hold political capital, and thus, promote a strong form of self-regulation. One example of this is stressing provider autonomy when it comes to patient eligibility criteria. For instance, ASRM has stated: "It is ethically acceptable for clinicians, based on their evidence-based and unbiased assessments of risk, to decline to provide fertility treatment to women at high risk of complications in themselves or their children" (ASRM, 2022: 715).

However, ASRM's approach to self-regulation rather tackles one specific part of governance, namely the level of already effectively issuing such guiding rules. They have the authority and the mandate to actively regulate specific areas in ART together with SART and other affiliated societies in the field of ART, while in cooperation with the Centers for Disease Control and Prevention (CDC). They very actively advocate for a particular form of self-regulation, namely, on the one hand, the requirement that the mandate for decision-making (and the power to define) must remain within the profession, primarily oriented by the ASRM guidelines, and, on the other hand, they place a strong emphasis on "provider autonomy" (as they would put it), within the context of medical practices (i.e., physician practices and individual clinics). This includes the often-recommended self-responsible publishing of written policies by physicians and their clinics themselves that should define the conditions under which a clinic or medical practice would offer and practice particular treatment options. Following their argument, clinics should orient themselves based on rules and recommendations issued by them (ASRM)

[109] Preimplantation genetic diagnosis. http://americanpregnancy.org/infertility/preimplantation-genetic-diagnosis/ (accessed on 19th May 2018).

as the leading actor and the association for the professional community in this field because they are deemed the most knowledgeable and appropriate stakeholders in this domain who should have the final say (or, at least, an important say) in their perspective.
ESHRE, in contrast, argues on a different, 'broader' level about where they want to see their justifications and recommendations located, namely deployed in such a way that they might be useful in different places (European countries) within different medical legislations and cultural environments. The model of (self-)governance in the case of EHSRE addresses a much broader level of *the ways how policy and regulation are or might be done*. This entails a specific imagination of policy and regulation itself, namely how they want to locate themselves *in this discourse and imagining what regulation could look like* in the context of the EU as a supranational Union. Of course, they formulate more or less concrete recommendations for clinicians and practitioners, but more importantly, also broader considerations of how specific issues might be meaningfully regulated and addressed in the European space, as a specific kind of conglomerate of different national legal policies, and not just how this might be done in individual clinical contexts. An example would be 'cross-border reproductive care' within the EU as a safety valve for access to treatments while circumventing domestic restrictions and recognizing value pluralism (Pennings, 2004). They very much consider governance questions themselves, and what regulation could look like at a European level when thinking and questioning principles of practice. They also think about who could or should be in a position to guide clinical practice orientation. As a major international scientific society in this field, ESHRE certainly sees itself in taking and having a strong position to be a key leading actor in issuing-making, and thus, establishing guiding rules for governance.

Coming full circle, the aim of this rather concise subchapter was to provide a (necessarily patchwork-like) overview of the various legal and regulatory aspects and environments in which the field of IVF and reproductive technologies are embedded in the US and Europe and the context of the EU. It is this very fragmented regulatory situation that builds the medico-legal environment in which these scientific actors operate, think and argue. That necessarily has to be considered when drawing a connection between making human reproduction through the treatment of infertility (and its ethical acceptability) a governable issue through and within the work of these ethics committees (in particular their ethical papers and the imagined idea of (self-)governance that resonates within these papers).
It is precisely this regulatory patchwork in both cases that builds the fertile ground for these scientific actors to impact the governance of human reproduction. On the one hand, this regulatory environment constitutes a crucial condition for the steering capacity of these scientific actors, so that they can, in addition to other actors or areas (such as law and politics), occupy this regulatory limbo with their professional expertise, precisely because they are interested in steering the field. On the other hand, it is also their interest to steer this field (expressed, among others, through these ethics papers) through their active role aimed at having an impact on policy-makers and taking or maintaining their active role in defining the regulatory situation(s). They are doing this by creating, shaping and issuing ethical rules and expert recommendations in and for their field – gaining through these (bioethical) practices

both importance and a significant role in governing the field of human reproduction and its technologies.

In this context, it is of utmost importance to reflect on the specific relationship between bioethics, law and politics and on the possible function and role of bioethics in relation to these other fields. Specifically looking at them as a potential kind of intermediary or boundary actor. For example, Petra Gehring has raised the question of whether bioethics should be seen as an open-ended real experiment of legal policy. This is to say, as an additional tool in the political sphere itself which makes vivid offers, reworks problems and creates – not always, but sometimes – politically attractive alternatives to the law (Gehring, 2016: 159). She notes that:

> It [bioethics] is successful in the run-up to and in the environment of parliamentary norm-building, partly accelerating, partly slowing down, and especially successful where politics governs not through laws but, as in the case of doctors' and patients' rights, through soft regulations. (ibid., translated by the author)

This is especially true in the field of human reproduction and reproductive technologies, which is why I would like to further reflect on the aspect of the specific governance functions of such bioethics committees in the field of reproductive medicine and the related question of responsibility in the final discussion section of the thesis. I will do this in a rather 'speculative' way because these developments are still ongoing and thus my study can only provide some insights into the particular cases at hand. In addition, I would like to conclude by pointing to something I call *ethical evidence*, a term that I use to describe the result of this high concentration of written ethical expertise (the modes of justification as particular relevant statements in this discursive formation). Against this backdrop, I would like to address another very remarkable circumstance, namely the present absence of a tangible notion of technology (at least in an explicit form) within the bioethics discourse of these ethics committees, but I think this can be assumed quite generally.

Chapter 8: Ethical evidence: Ethics as a hybrid space of conflict transformation

Before I elaborate on the notion of ethical evidence in the context of my discourse analytic perspective on bioethics and its governance functions, I would first like to revisit a discussion from Chapter 4 about empirical bioethics and its critique of so-called 'traditional' bioethics. This may prove helpful in making the connection between aspects of effective self-governance and their role in making human reproduction a governable issue through their modes of justification. Then, I continue by discussing a striking feature of this discursive formation, namely its current lack of a concept of technology that goes beyond individual reproductive technologies around which bioethics usually groups and orders its problems and conflicts. In a final step of this concluding discussion chapter, I will close with some thoughts about the scope, relevance, and multiple associations my study has created.

8.1 Making human reproduction a governable issue

A prominent social science critique of bioethics is whether the reasoning and judgements in bioethics positions and opinions actually represent the empirical ground of these concerns. Examples of issues that draw this critique include egg donation, cryopreservation, the moral status of the embryo, stem cells, transgender care, and equal access to treatments. Rayna Rapp (2004), demonstrated in her studies on prenatal testing for Down Syndrome that one of the least important issues that women struggle with when it comes to prenatal testing and abortion is the moral status of the embryo. This stands in stark contrast to the fact that the moral status of the embryo has been a characteristic concern of bioethical considerations from the very beginning (Hedgecoe, 2004; Rapp, 2004).[110] Hedgecoe pointed out, however, that bioethicists might object that while these women's understandings are powerful, they are subjective and emotional ideas that should not play a role in 'rational' ethical deliberation about prenatal testing.[111]

However, we could also say that these different actors – bioethicists and pregnant women who are confronted with a potential abortion due to prenatal testing – are operating in different 'orders of worth' (to once again mobilise the language of Boltanski and Thévenot (2000)) to justify their actions. Rapp accurately called these women "moral philosophers of the private", and therefore as sincere, applied philosophers because they have exactly to work through a moral dilemma by and of their own: "(…) using values and beliefs about morality to reach a decision that they then have to put into practice" (Hedgecoe, 2004: 137). These women, indeed, do apply their philosophy into practice. Yet, this constitutes a main difference to the bioethicists who are acting and operating not in the private but acting in different institutional

[110] However, the concerns of bioethicists are also changing and respectively the issues they are considering. The moral status of the embryo was a typical concern in the early 2000s, nowadays they are rather struggling with topics such as social egg freezing, equal and safety access to medical treatments, or 'cross-border reproductive care'. However, the moral status of the embryo appears in regular intervals and is always an issue whenever lines of research involving human tissues (such as stem cells) are discussed.

[111] Whether this statement is still true is an open question. I can imagine, also in view of my observations at ESHRE's congresses (patient sessions), that the reasons and concerns of women increasingly find their way into bioethical decision-making, but nevertheless there is a fundamental difference between the two.

and public spheres of society with a particular role to consider relevant issues, "(…) with a (potential) impact on patients, professionals and society as a whole" (ESHRE, 2019).[112] Through this, they, therefore constitute a potent part of public life. They are expected, so to speak, to develop solutions and propose decisions that go beyond the individual and think in collective terms.

In turn, it reflects very well what kinds of speakers (or speaker positions) are envisaged in such a bioethics discourse and are thus legitimized and authorized to express themselves within this discourse: ethicists, experts (such as scientists and physicians) and women concerned. It should be also noted that the embryo debate in the early 2000s was much more principle-based than, for example, other issues that have successively arisen in the field over the years, and where evidence-based justifications have become increasingly predominant, as we have seen. This can, in turn, also be problematic because not all problems and questions can be resolved with scientific evidence. Profound value conflicts and issues where multiple interests are at stake have to be weighed differently depending on the issue at stake and the different interests and value dimensions – in a very ethical sense. This leads to a third point, which is that the various questions that arise are not mutually exclusive but rather point to the fact that they are contextual, that is, they point to the situated nature of the various concerns – a pluralization of modes of concern (Stengers, 2011). Thus, good professionals must consider this state of affairs and relate both values and facts in their professional practice.

In this regard, Inthorn has noted that the discrepancy between public and professional discourse does not allow conclusions about the relevance of a question nor that from their combination a kind of completeness of arguments will result (Inthorn, 2013: 106). This discrepancy indicates a specific responsibility, particularly on the side of bioethics experts and professionals concerning issue-making and the provision of arguments and justifications that are always written and applied in and for specific contexts. According to Foucault, this involves specific forms of knowledge production and the question of which conditions lead to the circumstance that empirical knowledge as contextualisation of normative statements promotes certain forms of life (Foucault as cited in Inthorn, 2013).

Additionally, the moral status of the embryo in the bioethics discourse is a concern that has emerged rather out of a research context. That means, for a researcher who is doing embryonic stem cell research, or working with genome editing technologies, or even a clinic that is handling pre-implantation embryos and embryo screening, the question of the moral status of this entity and when it acquires such a status might be indeed a relevant question to consider. Alternatively, in a situation where a woman finds herself confronted with a diagnosis following prenatal testing, it is not a relevant question at all for deciding for or against abortion. Nevertheless, the irrelevance of this question in one context does not say so much about its relevance in another. This definitely cannot function as a legitimate basis to exclude professional discussion on particular questions, or vice versa. Rather, this example teaches us that, first, a question can be evaluated differently by different actors, and second, that different questions are at stake depending on the context from which it arises (patient and their life,

[112] See: https://www.eshre.eu/Home/Committees/Ethics-Committee, (accessed on 18th December 2019).

researcher within a particular research field, a physician or medical professional in a clinical context with particular duties (also in a legal sense) and responsibilities).
These reflections might create a sensitivity towards medical, clinical and research settings as multiple and complex spaces in which a variety of potentially relevant issues, and thus responsibilities arise that need to be considered in their full complexity, and what form of care might be needed for which concern.
As discussed in earlier chapters, both ethics committees heavily operate using the principalist approach and the informed consent procedure as important argumentative resources in their ethical approaches to evaluating various questions about the ethicality of medical practices and technologies in reproductive medicine. However, as we have also seen, these approaches very often fall short because they are tied too closely to scientific evidence as an overarching source of legitimacy. Furthermore, no matter how much information is put into an IC form, it cannot replace good communication and care. Good communication and care mean ensuring an adequate understanding of the information provided and a sensitive doctor-patient relationship. Again, Mol's analysis reminds us of the difference between a logic of care and a logic of choice, and of the problems that come along with a too strict separation between facts and values in the latter:

> So, the logic of choice tries to separate facts from values while the logic of care attends to them jointly. But there is more. Another striking difference is linked with this. The facts that the logic of choice wants to lay out represent a disease that is located within the patient's body. The fact-values[113] relevant to the logic of care cannot be laid out at all. Since they concern a disease that interferes with a patient's life, they do not refer to a three-dimensional object (a body) but to something historical (a life). (Mol, 2008: 47)

It is also a powerful illusion – but apparently also a great desire – that one can solve all the complex questions that are involved in this biomedical domain (with all its related medical technologies) with one and the same arguments and methods. But such complex questions, which are located at different levels, cannot simply be negotiated and governed by using one and the same approach. Examples of these intractable questions include: Who has access to which treatments based on which conditions (especially in the face of scarce resources in a given healthcare system)? Is a given reproductive technology (at a certain point in time) with unknown risks even desirable or reasonable to further pursue? Given the desire for genetic parenthood (the Achilles heel of ART), is it always and under all circumstances a legitimate reason to undergo IVF and similar procedures? And, finally, the question[114] of different treatment options and how to choose the right one? Obviously, all these questions are located at different levels and have different scopes, which makes it difficult to think them all through and justify them with the same instrument(s): the IC form, the biomedical principles and scientific evidence. These issues encompass a complex web of different levels, ranging from the

[113] With 'fact-values' Mol describes the following (in the context of Diabetes): "(…) blood sugar levels are fact-values. They acquire their significance from their relation to a standard: the normal blood sugar level. But this normative fact, the normal blood sugar level, is not a simple given either" (ibid.: 44). Also, the reason why one speaks about blood values and not facts. However, this 'normal' level has to be found and defined as well as its limits, so at which point normality stops and interventions should begin is not something straightforward either. In some cases and considering uncertainty in measurement this could be actually not the easiest thing to do.
[114] Last but not least, in 8.3 I will raise another, broader set of questions, again on a different level.

social to the individual to the economic, and also include a wide range of value issues. For some of these questions, these approaches and modes of justification are rather insufficient, because they are not able to address all the different needs, levels, and dimensions of these disparate issues. One conclusion might be that bioethics does not have to be the sole actor dealing with all of these questions. However, the complexity of regulating these issues emerging from ARTs is that they are intricately intertwined, making it difficult to strictly separate them. In this sense, the field of ART and the discourse of bioethics merely show the complexity of governing such emerging biotechnologies.

8.2 Ethical evidence

Discourse as an ordering practice is always material because it is a practice, which means that it has to be understood as an economy of power (Foucault, 1978); in this way, it also forms the very objects of which it speaks. After all that has been said, the question can now be asked again differently, or perhaps more succinctly, namely: if bioethics is the answer, what was actually the question? Bioethics did not emerge arbitrarily, as I have tried to highlight using my detailed analysis of the particular justificatory statements enacted in the ethical opinion papers of the two ethics committees in this study. But also through the many insights I gained from a range of field visits and conversations I had in the course of my research endeavour, as well as through what I revealed during a systematic literature review of the diverse facets of bioethics and its discourse. My study suggests that bioethics operates exactly as an experimental space for navigating and implementing potential new conflicts on emerging technologies, and as a very specific formation whose main function has been to respond to a kind of emergency at a given historical moment, in the sense of a whole new emerging network of biotechnologies.

Following Foucault's understanding of power as a technology, bioethics as a particular discursive formation can be viewed as such a technology of power because it makes something productive (and not prohibitive). This makes it an attractive offer or add-on in the political sphere itself due to its fluidity and its indeterminacy, so to speak, as a testing ground for how to deal with different technologies and their legitimation – two sides that can hardly be separated. Ethical decision-making, or let's say, *ethical evidence,* which finds its concentration in the form of *ethical opinion papers*, represents the process through which a particular emerging sociotechnical (biotechnological and moral) network becomes stabilized. The reason that I want to view these ethical opinion papers as *boundary objects* is because they bring together these different spheres in particular ways (ethics, science, politics and law) and, consequently, manifest themselves as a *hybrid zone of indeterminacy*.

Ethical evidence functions here as a boundary object because it constitutes a potential reference point for political, but more importantly medical, decision-making and, at the same time, for scientific knowledge claims. This ambivalence of a double referral context is also a characteristic feature of evidence-based policy (Rüb & Straßheim, 2012). In this sense, one can say that bioethics indeed operates as an experimental and laboratory conflict space for legal policy. It constitutes indeed an additional tool in the political sphere itself, which makes vivid

offers, reworks problems and creates – not always, but sometimes – politically attractive alternatives to law as a soft form of regulation.
However, the ethics committees in this study not only create alternatives and deal with problems, but they themselves create and generate new controversial (or conflicting) issues and objects. I have shown this with the example of "planned oocyte cryopreservation" (ASRM), and "fertility preservation for ovarian ageing" (ESHRE) as instances of issue modifications. A further example of this would be the modification of 'reproductive tourism' to 'cross-border reproductive care'. Re-evaluations of these issues are possible but only in an entangled manner and they are not reversible in a strict sense.
The bioethical work of these committees (the modes of justification) is essentially characterized by a specific form of indecision because the actual decisions must be made in the political sphere. Yet, ethics provides the ways and forms in which a decision might be made, i.e., above all, on what basis and with what kinds of arguments and justification it can be (or could) be made and thus, legitimately justified. Its relevance lies precisely in its non-binding nature because it develops and performs vivid offers to legal policy and soft governance tools (justifications, reasonings, legitimate arguments and positions) to the medical field and its associated professionals. These offers are characterized simultaneously by their non-binding but also their non-retrievable nature. In this sense, bioethics can be understood as an experimental space in the sense of putting to test different scenarios, models, concepts and understandings.

The legislation of ethical issues regarding reproductive technologies illustrates the uneasy mix of ethics and politics because ignoring pluralism in society is not an option. In this context, and to revisit an earlier thread here, the addition of the word 'law' in the name of ESHRE's former Task Force (on ethics and law) presents an interesting instance. They position themselves somewhere in-between these two spheres (ethics and law), which makes visible something quite important: the difference between *ethics* as a kind of rule-setting practice, (which implies rather a compliance with a rule or rules in the plural that should guide and steer actions) and *law*, which operates and is based on prohibitions. With this addition in the name of the former ESHRE TF (for ethics & law), they emphasize indeed how important it is for clinicians and researchers to take into account the legal landscape in their respective countries when applying ARTs. At the same time, with this addition, they also point out the co-productive nature of law and society. Legal regulations are also not stable entities, but are in permanent exchange with society, otherwise there would be no legal changes. Of course, legal regulations play a central role in both clinical and research practice and in the associated ethical considerations, because they constitute (or establish) kinds of binding elements or relationships between different actors and entities. But my work also argues for viewing these ethical opinion papers precisely as such technologies of power: Ethical opinion statements have a lot to do with this kind of (a soft or tacit form of) rule-making practice in a *productive sense*, precisely through the specific form of definitional, modification and justification work they perform when it comes to what is to be considered ethically (un)acceptable medical and/or research practice in the field of ART.

Bioethics forms the adequate discourse, as a discursive technology of control, for a particular understanding of technology: the use of (bio)technological intervention as a real experiment in the world. Bioethics effectively tests and enacts specific modes of justification and arguments (and their societal potency) for controversial and conflictual moral fabrics, which are thus in the process of emerging. It constitutes itself as the appropriate discourse, not only because it performs modes of justification for certain biotechnological applications, which produce *truth* statements, but also because it functions as a justificatory framework for a – permanent – mode of real experimentation of precisely these biotechnological interventions in society.

By viewing these ethical documents in this way, we can also understand them as kinds of *inscription devices*. As such, they fulfill their function as a governance instrument, precisely because of their characteristic of providing, framing and constraining (or modifying) interpretation. Understood in this way, these ethics documents then lead us to the question of which kinds of contexts, framings, and weavings become construed in which ways, where different things (such as human actors, biological entities, technologies, procedures and therapies, moral values) become specifically ordered, assembled, and located in space and time. I have argued that this is done through certain modes of argumentation, that is, primarily through the modes of justification. Scientific evidence, informed consent, and biomedical principles as the main modes and their variations serve to justify medical and actions and technologies as legitimate forms of medical and research practice. It is through these modes of justification that certain issues are enacted in the first place because it is the very act of justification that allows certain propositions to be uttered and repeated in certain ways and thereby gain validity and the status of true statements. Thus, the aggregation of data and the production of ethical evidence functions precisely as a profound truth regime in this domain. It also functions more generally, as we can see in many other social arenas as well, which is predominantly based on its supposedly objective character (Asdal & Reinertsen, 2022). Following Rüb und Straßheim (2012), this could be called justification through objectification (or scientification).

In this light, ethical evidence represents an interweaving of certain argumentative practices (scientific evidence, informed consent, ergo autonomy principle, and the well-known four principles approach) and other justificatory procedures (e.g. rules of deliberation, such as consensus or the composition of ethics committee members). These practices produce a specific hegemony of truth statements, i.e., how to argue, and thus, how to view and understand the use and effects of reproductive technologies. From this hegemony of truth arguments, we then try to learn what future normative worlds might look like and how to encounter and deal with these new or emerging technologies in the future present.

8.3 Absent notion of technology

As inscription devices, these ethical opinion statements (as particular kinds of documents through which ethical evidence is condensed and concentrated) themselves contain theoretical

reflections. Therefore, as a last point to this conclusion, I would like to highlight a circumstance that I noticed during my study of these specific documents: there is an present absence – there is no (conceptual) notion of technology in this particular discursive formation of bioethics.

Bioethics as a phenomenon of discourse has solidified and constituted itself in the form of ethics committees located at a variety of institutions. My case study investigated a very particular expression of this phenomenon: two scientific societies situated geographically in different places but both are operating in the field of human reproduction and taking part in the discourse on its emerging medical interventions (primarily but not exclusively in the form of their ethics committees and their written bioethical work). I claim that one of the functions of these ethics committees and their paperwork is to make human reproduction a governable issue, through its manifold ordering practices of justification, which, at its core, consists of defining *ethical acceptance* of 'new' and emerging (bio)technology.

Interestingly, those ethics papers or committees themselves do not have or share a conceptual notion of technology, although their whole discourse and decision-making is constructed (as an effect) around a set of emerging ARTs. As pointed out, this very specific discursive formation whose main function has been to respond to a kind of emergency (at least so it seems) at a given historical moment, namely to respond to a whole new emerging configuration of biotechnologies and their serious effects (in the sense of their non-reversible character). Following Petra Gehring, one could claim that what makes these techniques so controversial is the product that results from its performance (so what is being argued about: the 'technology', as for example, the in-vitro embryo, sex selection, stem cells …).[115] With a non-reversible character, she describes the effect of these new reproductive technologies, i.e. that their 'controversial' specificity produces their own complex problems. For instance, with the invention of IVF, there was not only the possibility of procreation for infertile (or partially infertile) people in the world and with that the possibility that they could have genetically related children after all. But suddenly there was also a much more complex problem that transcended this individual technology, namely the connection between prospective knowledge and the possibility of exclusion/selection factually enabled by preference choice, which had never been discussed in principle due to a particularized and technology-bound discursive situation (Gehring, 2006).

This very much relates to the critique put forward by Evans that the bioethics profession has merely negotiated the means and not the ends of biotechnology (Evans, 2002, 2012). For example, the overarching problem of decisions on selection (future children, but also in the context of PGD, and current genetic testing) has never been discussed as such or in principle, because each issue is linked to a (new) individual technology. When this happens, it always turns out to be a problem or question of (patient) choice (i.e. autonomy principle, Informed consent …) in the context of this individual technology. But the problem of selection decisions

[115] "Technologies is deliberately called here - because concrete techniques do not have this specifying power. On the contrary, the concrete techniques that are applied in the laboratory are often rather strikingly similar across the technologies: whether it is a PGD gene check, an embryo experiment or cloning - the procedures (and also devices) in the laboratory hardly differ. Their final >>meaning<<, namely the product, makes of the techniques what is argued about: the >>technology<<" (Gehring, 2006: 135; translated).

is an issue that is never discussed on its own, and that is what is meant by non-reversible character. This is because, with IVF, that problem was suddenly in the world. In this way the bioethics discourse forms itself around these new technologies and remains bound to the individual technologies and does not enable a broader debate about overlapping themes – trans-technologically, so to speak.[116]

Thus, if we understand ethical evidence as a practice that produces truth arguments through its specific procedures by which a certain emergent network is discursively stabilized, then the lack of a conceptual notion of technology in the bioethical discourse is highly relevant. This is especially noteworthy because bioethics could even emerge as an alternative discourse formation in relation to technology assessment. This also reflects a kind of empty memory field of this bioethics discourse (Gehring, 2006), that it emerges as a necessary discourse to find ways to deal with these new technologies and the new social constellations and problems that come along with them. This gesture has a profound authorizing effect and gives the bioethics discourse the maximum power of definition since it does not offer any form of historical comparison or benchmark.

As we have seen, the bioethics discourse operates with a bundle of normative categories, including: autonomy, dignity, justice, freedom of choice, and many more, but it conspicuously lacks a notion of technology (or even a theory of technology). This is in some ways its blind spot. What my study has also tried to show is that there is indeed a common thread in their argumentation recognizable, namely a unifying logic of choice that also holds this discourse together and which is based precisely on the principle of autonomy. It is on the basis of this logic that bioethics makes and structures its decisions. This means that bioethical decision-making and its positioning is, on the one hand, bound to the new or emerging technologies, which in any case always requires a new positioning, because of a lacking notion of technology as well as a lack of dealing with the overarching problems that these ARTs produce. On the other hand, when considering their language games in the context of wider healthcare logics (as I have attempted to do in Chapter 7), it does indeed follow a broader logic of choice that profoundly structures its argumentation and positions, making them more coherent and robust (i.e., justified) positions than they may seem at a first glance.

In conclusion, their particular language game is essentially one of justification, one that increasingly invokes scientific evidence and data and bases their justificatory work on these resources in order to make them even more credible and legitimate. At this point, I will return to the anecdote I told at the beginning of my work (in Chapter 2), where I told the story of how one of the ethicists of the EHSRE group mentioned that STS-scholars could be relevant scholars for such (institutionalized) ethics work. My contention now would be that it has precisely something to do with the lack of a theory of technology in bioethics. This makes the conceptual STS knowledge of technology (its trans-technological study interest so to speak) a meaningful

[116] It is worth noting that Gehring calls them 'causing' technologies ("Verursachertechnologien"), but in the context of the ethics committees of this study in the field of ART, I would tend to call them rather 'enabling' technologies.

and relevant player for such bioethical work because this constitutes definitely a blind spot in bioethics in general.

8.4 Coming to an end – scope, aim and relevance of this study

A few years ago, the increasing talk about ethics related to these emerging biotechnologies in the media and in science piqued my interest. My project started with the question of why these technologies, especially those in the field of (assisted) reproductive medicine, are primarily discussed in an 'ethical' framework rather than, say, a risk framework or a medical and scientific framework. Gradually, it became clear that my interest was primarily centered on so-called bioethics (as a particular discursive formation) which constitutes itself around these new technologies. This is the point from which my project started and unfolded. I searched for possible cases, materials, questions, and conceptual and methodological tools to find out and get closer to the thing I am interested in, which merged into two broader overlapping questions: *how to understand bioethics* (as a discourse, and that means, as a (soft form of) governance practice)? And *how is it performed* in a concrete case study (the ethics committees of the ESHRE and ASRM), and *how do they come to define and justify what they deem as ethically (un)acceptable research and medical practice and morally justifiable decisions and positions in the field of medically assisted reproduction*?

There are two aspects that I would like to emphasize in this regard: the *first* is what I have already mentioned at the beginning of the thesis but what I would like to re-emphasize now, namely the distinction between ethics and morality in this question. For me, this distinction is not primarily crucial, but I deliberately chose to call it "morally justifiable decisions" because I do think that what the ethics committees base their decisions on (scientific evidence, which in their case means primarily data; informed consent, and principles) can certainly be called moral. This is because it sets values like: scientific knowledge as a reliable basis for ethical considerations, or informed consent, that is, patient autonomy in the form of patient choice, as commonly shared values. The bioethics discourse not only represents an ethical examination about what is right and wrong but also promotes or subscribes to something like 'secular' values, which are upheld in liberal democracies and Western medicine and healthcare.

The *second* point I would like to re-emphasize in an explicit manner is that, little by little, I realized that there is a constantly rotating question involved, namely whether bioethics constitutes a discourse in a Foucauldian sense? I tend to answer this question – which no one will be surprised by now – with a yes. But this yes has serious methodological implications: what does it mean if something is a discourse in Foucault's sense? If we follow Foucault in a serious sense, then this is only demonstrable after having done a so-called statement analysis through which the regularities of a discursive practice should become intelligible (as the statement is defined as its function of existence). It is this function that I have tried to study and describe in detail. This means studying and describing the actual practices, conditions, rules and variations that govern the statement(s) and the field in which it operates. This also includes how and when the three argumentative modes of justification and their variations can be repeated, in which forms this is done, and with which modifications this is performed. It is exactly this meticulously

studied field of statements that reveals bioethics as a particular discursive formation, in the sense that its specific identifiable statements builds the field of its stabilization – the discourse.

Now to the scope and the relevance (and potential limits) of this study. It is limited or let's say, *situated,* in the sense that I investigated the local expression of bioethical reflection and decision-making in the two cases of ESHRE and ASRM (both of which are scientific societies). It is difficult, but also not the aim of this study, to raise the claim that this counts for every bioethical debate or institution. However, what my study can indeed provide is a reference point with which to take this analysis further and look at how useful it could be for investigating further cases of bioethics expertise, providing points of contrast, comparison or orientation for other sites and situations (Mol, 2008). Therefore, its relevance is not only local but indeed of wider interest as it potentially becomes a part of a trajectory or path. As Mol put it, "It is the very specificity of a meticulously studied case that allows us to unravel what remains the same and what changes from one situation to the next" (ibid.: 9).

In this regard, I will finally bring the notion of the local/global[117] into play, which, in STS, refers to the point that scale, type, number and topography of connections are left to the actors themselves which the analyst then tries to follow. This lifts "the tyranny of social theorists and to regain some margin of maneuvers between the ingredients of society" (Latour, 1996: 373). However, the analyst also chooses which connections to follow, and in this sense, I will re-emphasize the importance of Stengers notion of 'rapport' – which is the name for the comparative connections that become assembled by the researcher and the researched (or the analyst and the thing to be analyzed). This is a difference which gets lifted or which is at least vague (and unimportant to a specific degree) in an ANT-based research style.
In my analysis, 'rapport' is something I actively have created between the two cases at hand, namely by bringing them into a particular kind of conversation, into a specific comparative relation through different strategies, concepts, modes, and material of my research approach and by the framing of my research interest. Having done so, I brought these two ethics committees, and their numerous ethical opinion statements into conversation and they brought me to create with them a specific kind of relation. I take total responsibility for these untold decisions I took in the course of my seven-year-long journey of doing this research and analysis. Or, in other words, initially an undivided interest, entirely occupied in preserving bioethics as a good object of study (practice of discourse and discourse as governance practice), "it subsequently splits into two diverging and reconverging desires, one of which 'looks' at the other; this is the theoretical break, and like all breaks it is also a link: that of theory with its object" (Metz, 1982: 79).
Linking knowledge production with the creation of a 'rapport' (or rapports), in Stenger's sense, allows for a pluralization of modes of concern associated with this rapport, and the assertion that what is operationally defined 'lends itself' to this correlation (Stengers, 2011).

[117] "(…) the notion of the network allows us to think of a global entity -a highly connected one- which remains nevertheless continuously local…" (Latour, 1996: 374).

It is important for me to emphasize this state of affairs because there are countless decisions and associated responsibilities that everyone must make every day when they step out of the front door – including the scientist. There is no point or place where one can escape the need to make choices and decisions, and to say so would actually make the importance of responsible decisions impossible. The pluralization of modes of concern associated with these rapports points to the political dimensions of these countless research decisions and their power to produce knowledge.

In this sense, I take responsibility for having applied such a rigorous analytical view to the bioethics expertise present in these ethics committees. My work focused on how they function, their inner workings in these specific cases, and, in particular, their decision-making (i.e. their justificatory work). I hope that my study will make a bountiful contributions to the field of STS, as well as to bioethics. I have always endeavored to do my work and treat my participants (and the documents) in a respectful manner because I am genuinely impressed by the demanding work and debates that these ethics committees handle. They take great care to address the manifold issues that arise in the field of reproductive medicine and its associated technologies. However, I also think it is important to highlight the potential shortcomings of the bioethics discourse, especially if we consider it as a governance practice that actually helps to guide both medical decision-making and regulatory approaches in the field of ART.

In particular, the strong pursuit of evidence-based justifications and their relationship to other arguments, such as principles, needs to be carefully considered. This consideration should include, for example, what and how new treatment options, products, or research lines are funded and developed (and which ones are not and why). It is important to make visible the underlying values that inevitably inform those very biomedical decisions. Scientific evidence does indeed play a critical role in developing and evaluating technologies and medical treatments, but, as a society, we should think about how and in what ways it can(not) support and affect those decisions (and by which values this evidence itself is formed). It is also clear that debates about values and how to weigh them hold us together as a society. Therefore, it is also crucial to include different values and publics in these debates. At a time when we are experiencing rapid technological changes, the question of how we should protect the values that bind us together is ever more important, as Sarah Franklin has already reminded us. These are the “real facts of life” that we need to understand, and which are more complicated than they seem (Franklin, 2019). It is my hope that these reflections will create a sensitivity towards medical, clinical and research settings as multiple and complex spaces in which a variety of potentially relevant issues, and thus concerns, arise that need to be considered carefully in their full complexity and what form of care might be needed for which concern.

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Annex

I Abstracts

English

Bioethical decision-making in assisted reproductive medicine is a delicate matter. To this end, this work explores how bioethical issues in reproductive medicine are negotiated, and thereby made by biomedical professionals (primarily so-called 'ethicists'). It is designed as a comparative qualitative case study examining two international scientific societies in the field of reproductive medicine and focuses on their internal ethics committees and their work. In particular, the main research interest lies on the various modes of justification with which it is defined what an ethically (un)acceptable medical and/or research practice should mean in the context of reproductive technologies. Following an actor-network theory approach, the thesis makes the methodological move to put documents – the ethical opinion statements of these committees – center-stage and views them as integral actors of making the very notions, issue(s) and objects that are at stake. Inspired by Boltanski's and Thévenot's pragmatist philosophy of knowledge and work on justification, as well as by Foucault's understanding of discourse as a practice, the thesis considers bioethics as a particular discursive formation. With a co-production perspective, it utilizes the normative discourses around reproductive technologies as a vehicle to analyze the knowledge production and power dynamics involved in this specific bioethics discourse. In this view, bioethics becomes a particular mode of governance practice and thus a phenomenon of power. Hence, this analysis is centered on aspects of governance and self-regulation of this techno-medical field. This also involves facing broader questions of how societies in general encounter new (or emerging) technologies and regulate their use, and what role and function (institutionalized) bioethics play in this. Bioethics can be seen as an additional tool in the political sphere itself which makes vivid offers, reworks problems and creates potentially attractive alternatives for political decision-making.

German

Bioethische Entscheidungsfindungen in der assistierten Reproduktionsmedizin sind eine heikle Angelegenheit. Im Zentrum der vorliegenden Arbeit stehen daher zwei internationale Fachgesellschaften im Bereich der Reproduktionsmedizin, wobei der Schwerpunkt auf ihren internen Ethikausschüssen und deren Arbeit liegt. Sie ist als vergleichende qualitative Fallstudie konzipiert und untersucht, wie bioethische Fragen in der Reproduktionsmedizin von Fachleuten (vor allem sogenannten ‚Ethikern') verhandelt und entschieden werden. Das zentrale Forschungsinteresse liegt dabei insbesondere auf den Rechtfertigungsmodalitäten, mit welchen versucht wird zu definieren, was im Kontext der Reproduktionstechnologien als ethisch (un-)vertretbare medizinische und/oder Forschungspraxis gelten soll. Im Stil der Akteurs-Netzwerktheorie wird in dieser Arbeit der methodische Schritt unternommen, Dokumente – insbesondere die ethischen Stellungnahmen beider Ethikkommissionen – in den

Mittelpunkt des analytischen Interesses zu stellen. Die ethischen Stellungnahmen werden als integrale Akteure in der Herstellung von Problemstellungen, Begriffen und Gegenständen betrachtet. Inspiriert von Boltanskis und Thévenots pragmatistischer Wissens- und Rechtfertigungsphilosophie sowie Foucaults analytischem Verständnis von Diskurs betrachtet diese Arbeit Bioethik als eine besondere diskursive Formation. In einer Koproduktions-perspektive nimmt die Arbeit die normativen Diskurse rund um Reproduktionstechnologien als Vehikel, um die Wissensproduktion und Machtdynamiken zu analysieren, die in diesem spezifischen Diskurs der beiden Ethikkommissionen zum Ausdruck kommen. In dieser Perspektive wird die Bioethik zu einem bestimmten Modus der Governance und damit aber auch als Ausdruck eines spezifischen Machtphänomens verhandelt. Daher liegt der Fokus auch auf Aspekten der Governance (Steuerung) und Selbstregulierung dieses techno-medizinischen Feldes. Somit geht es auch um die umfassendere Frage, wie Gesellschaften im Allgemeinen neuen (oder emergierenden) Technologien begegnen und ihre Nutzung regulieren, und welche Rolle und Funktion die Bioethik und deren Institutionalisierung dabei spielen. Die Bioethik kann als ein zusätzliches und formenreiches Instrument im politischen Bereich selbst betrachtet werden, das bestimmte Angebote macht, Probleme bearbeitet und modifiziert und damit potenziell attraktive Alternativen für politische Entscheidungsprozesse erarbeitet.

II Tables

III Material

All materials and documents listed here are also freely available on the websites of both organizations.

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IV Abbreviations

AM	Annual Meeting
ANT	Actor-Network Theory
ART	Assisted Reproductive Technology
ASRM	American Society for Reproductive Medicine
CBRC	Cross-border Reproductive Care
CDC	Centers for Disease Control and Prevention
COVID-19	Coronavirus Disease 2019
EACC	European Assisted Conception Consortium
EBM	Evidence-based Medicine
EC	European Commission
ELSI/A	Ethical, Legal, Social Implications/Aspects
ESHRE	European Society of Human Reproduction and Embryology
EU	European Union
ExCo	Executive Committee
FCSRCA	Fertility Clinic Success Rate & Certification Act
FDA	Food and Drug Administration
GIFT	Gamete intra-fallopian transfer
GMO	Genetically Modified Organism
hESC	Human Embryonic Stem Cells
HFEA	Human Fertilisation and Embryology Authority
HIV	Human Immunodeficiency Virus
HGP	Human Genome Project
IC	Informed Consent
ICSI	Intracytoplasmic Sperm Injection
IVF	In-Vitro Fertilisation
LGBTIQ*	Lesbian, gay, bisexual, trans, intersex, queer*
MAR	Medically Assisted Reproduction
MD	Medical Doctor
NSA	Non-state Actor
OC	Oocyte Cryopreservation
OECD	Organisation for Economic Cooperation and Development
PACS	Political Action Committee
PGD	Preimplantation Genetic Diagnosis
PGT-A	Preimplantation Genetic Test for the detection of Aneuploidy
RCT	Randomized Controlled Trial
RRI	Responsible Research and Innovation
SART	Society for Assisted Reproductive Technologies
SEEM	Safety, Ethical, Efficient, Moral
SIG	Special Interest Group

SMRU	Society for Male Reproduction and Urology
SREI	Society for Reproductive Endocrinology and Infertility
SRBT	Society of Reproductive Biologists and Technologists
SRS	Society of Reproductive Surgeons
STS	Science and Technology Studies
TF	Task Force
US	United States
UK	United Kingdom
WHO	World Health Organisation